TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING & VALIDATION OF LAB EQUIPMENT (PHASE-IV)

DOCUMENT NO: NPI-120310-EQP-S1-22
REV NO. 00
DECEMBER 2017

Project:
INTEGRATED VACCINES COMPLEX
AT
CHENGALPATTU
(Project No.: 120310)

INDEX

SECTION I
Notice Inviting Tender (NIT)
HLL Biotech Limited.

INVITES TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF LAB EQUIPMENT (PHASE-IV) AT HLL BIOTECH LTD, CHENGALPATTU

Tenders are invited from vendors for Supply, Installation, Commissioning and Validation of following Equipment's:

Schedule No	Equipment name	Capacity	Qty	EMD (in Rs)
I	Vortex Mixer		2	2,600.00
II	Table top cooling centrifuge	1.8 ml to 50 ml	1	24,000.00
III	Bag sealing machine		2	9,600.00
IV	Deep freezer (Ultra low)	250 Lts	11	77,000.00
		400 Lts	1	8,000.00
V	Hot air oven	200 Lts	1	7,000.00
		500 Lts	3	23,400.00
VI	Peristaltic pump	Flow rate: 100-3000 ml/min.	13	57,200.00
		Flow rate: 1000-10000 ml/min.	5	38,000.00
		Flow rate: 0-3 l/min.	10	44,000.00
VII	Air Sampler		11	88,000.00
VIII	Apo trinocular stereomicrosc ope		1	24,000.00
IX	Chiller water bath	20L	1	4,000.00
X	Conductivity meter	Should be operated at 80^{0}C	7	25,500.00
XI	Cooling centrifuge	6 lts (1.5*4)	1	48,000.00
XII	Cooling batch centrifuge	Floor mounted, 6lts, rpm 10000 max.	3	1,80,000.00
XIII	Deep freezer (Low)	250 lts	2	12,000.00

Schedule No	Equipment name	Capacity	Qty	EMD (in Rs)
XIV	Deep freezer (Low- Horizontal)	460 lts	3	21,000.00
XV	Egg Incubator	1000 eggs	1	30,000.00
XVI	GMP Refrigerator	300 L	8	71,500.00
XVII	Gas Chromatograp hy		2	1,40,000.00
XVIII	HPLC system		1	56,000.00
XIX	Incubator	200 Lts	3	72,000.00
		800-1000 L	6	1,44,000.00
XX	Inspissator		1	14,000.00
XXI	Inverted fluorescence microscope		1	32,000.00
	Upright Microscope		2	12,000.00
	Inverted microscope		4	24,000.00
XXII	LN2 storage container	-70^{0}C, 180 L, Vertical	4	51,500.00
XXIII	Magnetic stirrer with hot plate	To hold 20L glass bottle capacity	1	2,000.00
XXIV	Magnetic Stirrer	To hold 20 L bottle	4	24,000.00
		To hold 5L, 15 L bottle	2	12,000.00
		platform 400mm 50 L carboy with RPM 0-1200	11	66,000.00
XXV	Micro Aerophilic condition incubator		2	48,000.00
XXVI	PCR		1	18,000.00
XXVII	pH & Conductivity meter		5	15,000.00
XXVIII	pH meter		8	19,500.00
XXIX	Refrigerated Shaker Incubator (vertical)	2Litrs *6 flask	1	16,000.00

Schedule No	Equipment name	Capacity	Qty	EMD (in Rs)
XXX	Roller culture Apparatus		4	2,18,000.00
XXXI	Shaker Incubator	200Lts	1	13,000.00
XXXII	Spectrophoto meter UV with CPU	200-1100nm	2	18,000.00
XXXIII	Table top centrifuge	1 ml tubes	1	36,000.00
XXXIV	Thermohygro meter		28	1,700.00
XXXV	Ultra sonication bath	12.2 L	1	4,500.00
XXXVI	Vacuum Pump		1	2,000.00
XXXVII	Potentiometer		1	5,000.00
XXXVIII	Water bath	20 to 100 ˚C	2	10,000.00
		30 L	2	10,000.00
XXXIX	Weighing Balance	220g	2	16,000.00
		810g	1	8,000.00
		410g	1	8,000.00
		220g	1	8,000.00
		150Kg	1	8,000.00
		15Kg	1	8,000.00
		1 g to 600g Readability - 1mg	3	8,000.00
		10g to 10Kg (Readability - 100mg)	1	8,000.00
		0.1 to 1000 g	1	8,000.00
		0.1to 40 kg	5	8,000.00
		3-20 kg	1	6,800.00
		Upto 3 Kg	1	4,000.00
		0.1to 40 kg	1	8,000.00

Note: The list may vary (increase / decrease) during order finalisation.

Details regarding important dates are as follows:

Sl No.	Description	Schedule
i.	Pre Bid Meeting Date & Time	04.12.2017 (For Sch I to X) 05.12.2017 (For Sch XI to XX) 06.12.2017 (For Sch XXI to XXX) 07.12.2017 (For Sch XXXI to XXIX) @ 11:00 Hrs
ii.	Pre Bid Meeting Venue	**HLL Biotech Limited,** **Integrated Vaccine Complex,** **SF 192-195, Tirumani Village** **Chengalpattu -600 301**
iii.	Closing date & time for receipt of Tender	26.12.2017 (For Sch I to X) 27.12.2017 (For Sch XI to X) 28.12.2017 (For Sch XXI to XXX) 29.12.2017 (For Sch XXXI to XXXIX) @ 11:00 Hrs
iv.	Time and date of opening of Techno-Commercial Bids	26.12.2017 – 29.01.2017 @ 11:30 Hrs
v.	Venue of Opening of Techno Commercial Tender	**HLL Biotech Limited,** **Integrated Vaccine Complex,** **SF 192-195, Tirumani Village** **Chengalpattu -600 301**

Interested parties may visit www.lifecarehll.com / www.hllbiotech.com to download the Tender. Subsequent amendments/ addendum if any will be published in these websites, the parties are advised to visit the website regularly for updates. Tenders in sealed envelopes super scribing,

"Tender for Supply, Installation, Commissioning and Validation of Lab equipment (Phase-IV) for Integrated Vaccines Complex, Chengalpattu"

may be submitted to the address mentioned in Serial no. v of the table above.

INSTRUCTIONS TO BIDDERS

1. The successful bidder will have to enter into a written Contract / Agreement with the Purchaser, the terms and conditions of which are enclosed herewith.

2. The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialed/stamped.

3. Bidder must be careful to deliver a bonafide tender. Any tender which proposes any alterations to any of the conditions laid down which proposes any other conditions or any description whatsoever is liable to be rejected.

4. Intimation of tenders' quotation by a telegram/fax will not be considered.

5. Tenders must be accompanied by a certified true copy of the Power of Attorney in favour of the signatory to the tender which should interalia empower him/her to bind the firm to Arbitration Clause given in the Articles of Agreement and Contract conditions.

6. In case a blank tender is being submitted, it should be marked prominently **'BLANK'** on the envelope and signed by the authorized person.

7. In view of postal and other delays, the tenders should be posted sufficiently in advance of the last date fixed for receipt of tenders or be sent by a special messenger. Tender received late shall be liable for rejection.

8. Prices shall be written in ink and shall be entered both in figures and words. In case of discrepancy the figure quoted in words shall be taken as accurate. In case of any discrepancy in the unit and amount, the unit rate shall be taken as accurate.

9. Prices quoted by the bidder shall be firm and valid even if the contract is split in two or more parts among different bidders.

GENERAL INFORMATION

PROJECT LOCATION	HLL BIOTECH LIMITED, CHENNAI INTEGRATED VACCINES COMPLEX, CHENGALPATTU
PROJECT TITLE	INTEGRATED VACCINES COMPLEX, CHENGALPATTU
CORPORATE OFFICE	**HLL Biotech Limited,** **Integrated Vaccine Complex,** **SF 192-195, Tirumani Village** **Chengalpattu -600 301,Ph no. 044-22544949** **Email:** ramanr@hllbiotech.com
CLIMATE :	Maximum Temperature: 39.4°C Minimum Temperature: 18.3°C
ACCESS TO SITE :	By Road (Chennai to Chengalpattu GST Road). Nearest Railway Station is Chengalpattu Nearest airport is Chennai

1. Introduction

HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India, is implementing "an Integrated Vaccines Complex (IVC) - a project of national importance' at Chengalpattu, near Chennai. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India.

HLL Biotech Limited has associated with NNE Pharmaplan India Limited, hereinafter called as "NP" has been appointed as "Engineering Consultants". NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices. This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian FDA (Schedule M), WHO/GMP regulations.

One amongst the several other jobs is to supply, install and commission the equipment's / systems.

The scope of work involved is detailed in the subsequent paragraphs and is precise to the extent possible. However, it is expected from the supplier to consider and supply all those required for successful installation and functioning of the equipment / system.

2. Scope of Vendor

- The scope of vendor would be to comply with the enclosed URS, Plan, Supply, execute commission & validate the system as per URS and drawings.

- Quote for the unit against the URS, along with all options. The price to include all spare parts; documentation; packing; freight charges; start-up & commissioning; complete qualification package (FAT, SAT, DQ, IQ, OQ, PQ) and training and charges whatsoever required to complete the task in all respects to ensure the equipment operation is in accordance with the requirements of design documents.

- Involve with the purchaser and the consultants to establish documented evidence that the proposed design of the system is in compliance with the GMP requirements mentioned in the User Requirement Specification, Installation requirement specification and Risk Analysis.

- The complete system should be fabricated and installed as per design review report and the regulations mentioned in the URS (Under point number 2.0) and ultimately allows to validated as per NPI Validation philosophy prepared based on Indian FDA (Schedule M), WHO/GMP regulations

- Quality and Project Planning: The Quality and Project Plan should define the activities to be performed, their timing, who will perform them, the control mechanisms to be used, and the deliverable items. Project Time Schedule must be created for that purpose. This document should define:
    - ✓ Project Milestones
    - ✓ Project Activities
    - ✓ Planned start and end date of each activity
- Quality Assurance activities during manufacturing: E.g. Collecting the material certificates, surface roughness certificates, weld documentation, etc.

- System Build (assembly and system integration): The final assembly of the mechanical, electrical, and control components (hardware and software) into an integrated functional system should be performed by the vendor – according to the design documentation and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams).

- Construction Review: The integrated functional system is reviewed against the design documentation of the component manufacturers and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams). QC inspection and test reports

- Testing: Vendor to describe testing not related to specific user requirements, but which is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of pressure vessels. Details as follows:

  a) Pressure Vessel Testing: Prior to System Build, the pressure vessel should be subjected for pressure test in accordance with the applicable Pressure Vessel Code.
  b) Functional Testing: The Functional Testing is not related to specific user requirements, but is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of the system.
  c) Factory Acceptance Testing: The Factory Acceptance Test is a important milestone. The following tests and inspections will be performed but not limited to:

     1. Inspection to verify that all deliverables are available for shipping
     2. Inspection to verify that the correct system was built
     3. Testing to verify correct operation

  d) Note: FAT is critical to the delivery on time and equipment performance.

- Installation: Installation is a set of activities that have to be completed before site acceptance testing can start. Such activities include: putting in place, leveling, connecting media (including electrical power), turning on media and checking for leakages, fixing any leakages, checking direction of rotation for electrical motors, calibration, etc. The installation –has to be performed by the vendor.

- Pre-Delivery Inspection and Final Inspection: The Final Inspection should be the last quality related activity performed before delivery to the user site and thus need to be performed after Factory Acceptance Testing.

- **Turnkey (if any): Supply, Installation, Commissioning and Validation of Lab equipment (Phase-III)**

- **Project Management: Activities or the procedures to be followed, and responsibilities relate**d to Project Management are as follows:

  a) **Project communication:** Biweekly project update should be provided by the vendor in the early stage of this project.
  b) **Communication paths:** In general, all communication of the vendor shall be directed through the vendor Project Manager. The vendor Project Manager should forward the information as necessary.
  c) **Means of communication:** E-mail messages and facsimiles (fax) may be used for communication as alternatives to traditional letters and telephone conversations.
  d) **Sanctity of communication:** This also applies to decisions (e.g. approvals, accepted/rejected change requests, etc.), which always shall be communicated in writing. Such e-mail messages or facsimiles are considered equally binding as signed paper documents provided that the following data is provided:
     - The full name of the person making the decision
     - The date of the decision

- Progress reporting: See section Project Communication for details on how the progress may be communicated to the user company

- Documentation Management: Documents need to be trustworthy, reliable, authentic, and available for as long as required by applicable legal, regulatory, or business standards.

SECTION – II

GENERAL INSTRUCTIONS TO TENDERERS (GIT)

CONTENTS

A. PREAMBLE

1. Definitions and Abbreviations:

1.1 The following definitions and abbreviations, which have been used in these documents shall have the meanings as indicated below:

1.2 Definitions:

(i) "Purchaser" means the organization and / or its representatives (consultants) purchasing goods and services as incorporated in the Tender Enquiry document.

(ii) "Tender" means Bids / Quotation / Tender received from a Firm / Tenderer / Bidder.

(iii) "Tenderer" means Bidder/ the Individual or Firm submitting Bids / Quotation / Tender

(iii) "Supplier" means the individual or the firm supplying the goods and services as incorporated in the contract.

(iv) "Goods" means the articles, material, commodities, livestock, furniture, fixtures, raw material, spares, instruments, machinery, equipment, medical equipment, industrial plant etc. which the supplier is required to supply to the purchaser under the contract.

(v) "Services" means services allied and incidental to the supply of goods, such as transportation, installation, commissioning, provision of technical assistance, training, after sales service, maintenance service and other such obligations of the supplier covered under the contract.

(vi) "Earnest Money Deposit" (EMD) means Bid Security/ monetary or financial guarantee to be furnished by a tenderer along with its tender.

(vii) "Contract" means the written agreement entered into between the purchaser and/or consignee and the supplier, together with all the documents mentioned therein and including all attachments, annexure etc. therein.

(viii) "Performance Security" means monetary or financial guarantee to be furnished by the successful tenderer for due performance of the contract placed on it. Performance Security is also known as Security Deposit.

(ix) "Consignee" means the organization/person to whom the goods are required to be delivered as specified in the Contract. If the goods are required to be delivered to a person as an interim consignee for the purpose of despatch to another person as provided in the Contract then that "another" person is the consignee, also known as ultimate consignee. Consignee is HBL, Chennai.

(x) "Specification" means the document/standard that prescribes the requirement with which goods or service has to conform.

(xi) "Inspection" means activities such as measuring, examining, testing, gauging one or more characteristics of the product or service and comparing the same with the specified requirement to determine conformity.

(xii) "Day" means calendar day.

(xiii) "Employer" means HBL, Chennai.

1.3 Abbreviations:

(i) *"T E Document" means Tender Enquiry Document*
(ii) "NIT" means Notice Inviting Tenders.
(iii) "GIT" means General Instructions to Tenderers
(iv) "SIT" means Special Instructions to Tenderers
(v) "GCC" means General Conditions of Contract
(vi) "SCC" means Special Conditions of Contract
(vii) "DGS&D" means Directorate General of Supplies and Disposals
(viii) "NSIC" means National Small Industries Corporation
(ix) "PSU" means Public Sector Undertaking
(x) "CPSU" means Central Public Sector Undertaking
(xi) "LSI" means Large Scale Industry
(xii) "SSI" means Small Scale Industry
(xiii) "LC" means Letter of Credit
(xiv) "DP" means Delivery Period
(xv) "BG" means Bank Guarantee
(xvi) "ED" means Excise Duty
(xvii) "CD" means Custom Duty
(xviii) "VAT" means Value Added Tax
(xix) "CENVAT" means Central Value Added Tax
(xx) "CST" means Central Sales Tax
(xxi) "RR" means Railway Receipt
(xxii) "BL" means Bill of Lading
(xxiii) "FOB" means Free on Board
(xxiv) "FOR" means Free on Rail
(xxvi) "DAP" means Delivered at Place
(xxix) "DDP" means Delivery Duty Paid named place of destination (consignee site)
(xxx) "INCOTERMS" means International Commercial Terms as on the date of Tender Opening
(xxxi) "MOH&FW" means Ministry of Health & Family Welfare, Government of India.
(xxxi) "AMC" means Annual maintenance Contract (labour, spare and preventive maintenance)
(xxxii) "RT" means Re-Tender.

2. Introduction

2.1 The Purchaser has issued these TE documents for purchase of goods and related services as mentioned in subsequent paragraphs which also indicates, inter alia, the required delivery schedule, terms and place of delivery.

2.2 This section (Section II - "General Instruction Tenderers") provides the relevant information as well as instructions to assist the prospective tenderers in preparation and submission of tenders. It also includes the mode and procedure to be adopted by the purchaser for receipt and opening as well as scrutiny and evaluation of tenders and subsequent placement of contract.

2.3 The tenderers shall also read the Special Instructions to Tenderers (SIT) related to this purchase, as contained in Section III of these documents and follow the same accordingly. Whenever there is a conflict between the GIT and the SIT, the provisions contained in the SIT shall prevail over those in the GIT.

2.4 Before formulating the tender and submitting the same to the purchaser, the tenderer should read and examine all the terms, conditions, instructions, checklist etc. contained in the TE documents. Failure to provide and/or comply with the required information, instructions etc. incorporated in these TE documents may result in rejection of its tender.

3. Language of Tender

3.1 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, shall be written in the English language, unless otherwise specified in the Tender Enquiry. However, the language of any printed literature furnished by the tenderer in connection with its tender may be written in any other language provided the same is accompanied by an English translation and, for purposes of interpretation of the tender, the English translation shall prevail.

3.2 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, may also be written in the Hindi language, provided that the same are accompanied by English translation, in which case, for purpose of interpretation of the tender etc, the English translations shall prevail.

4. Eligible Tenderers

4.1 This invitation for tenders is open to all suppliers who fulfil the eligibility criteria specified against clause 16 of GIT Sec. II in this document.

5. Eligible Goods and Services

5.1 All goods and related services to be supplied under the contract shall have their origin in India or any other country with which India has not banned trade relations. The term "origin" used in this clause means the place where the goods are mined, grown, produced, or manufactured or from where the related services are arranged and supplied.

6. Tendering Expense and Tender fee

6.1 **Tender Expense:** The tenderer shall bear all costs and expenditure incurred and/or to be incurred by it in connection with its tender including preparation, mailing and submission of its tender and for subsequent processing the same. The purchaser will, in no case be responsible or liable for any such cost, expenditure etc regardless of the conduct or outcome of the tendering process.

6.2 **Tender Cost/Tender fee:** The tenderer should submit the tender fee of Rs.5,000/- (GST Extra) for National Bids or USD 100 for International Bids as on tender publishing date in the form of Demand Draft or Banker's cheque in favour of HLL Biotech limited, payable at Chennai. The DD/ Banker's cheque has to be enclosed along with the Techno-Commercial Bid which is non-refundable. In case of cancellation of tender by HBL, the tender cost/fee shall be refunded.

B. TENDER ENQUIRY DOCUMENTS

7. Content of Tender Enquiry Documents

7.1 In addition to Section I – "Notice inviting Tender" (NIT), the TE documents include:

- Section II – General Instructions to Tenderers (GIT)
- Section III – Special Instructions to Tenderers (SIT)
- Section IV – General Conditions of Contract (GCC)
- Section V – Special Conditions of Contract (SCC)
- Section VI – List of Requirements
- Section VII – Technical Specifications
- Section VIII – Quality Control Requirements
- Section IX – Qualification Criteria
- Section X – Tender Form
- Section XI – Price Schedules(Domestic, Imports, AMC, Turnkey)
- Section XII – Questionnaire
- Section XIII – Bank Guarantee Form for EMD
- Section XIV – Manufacturer's Authorisation Form
- Section XV(A) – Bank Guarantee Form for Advance Payment
- Section XV(B) – Bank Guarantee Form for Performance Security/AMC Security
- Section XVI – Contract Forms (Supply of Equipment - A & AMC – B)
- Section XVII – Proforma of Consignee Receipt Certificate
- Section XVIII – Proforma of Final Acceptance Certificate by the consignee
- Section XIX – Check List for the Tenderers
- Section XX – Consignee List
- Section XXI - Integrity Pact
- Section XXII - Instruction of Ministry of Shipping & Transport, New Delhi, India
- Section XXIII - Schedule of Fiscal Aspects

7.2 The relevant details of the required goods and services, the terms, conditions and procedure for tendering, tender evaluation, placement of contract, the applicable contract terms and, also, the standard formats to be used for this purpose are incorporated in the above-mentioned documents. The interested tenderers are expected to examine all such details etc to proceed further.

8. Amendments to Tender Enquiry documents

8.1 At any time prior to the deadline for submission of tenders, the purchaser may, for any reason deemed fit by it, modify the TE documents by issuing suitable amendment(s) to it.

8.2 Such an amendment will be notified in the website of www.hllbiotech.com / www.lifecarehll.com. The interested parties are advised to regularly visit the website for further updates.

8.3 In order to provide reasonable time to the prospective tenderers to take necessary action in preparing their tenders as per the amendment, the purchaser may, at its discretion extend the deadline for the submission of tenders and other allied time frames, which are linked with that deadline.

9. Clarification of Tender Enquiry documents

9.1 A Tenderer requiring any clarification or elucidation on any issue of the TE documents may take up the same during the pre-bid conference. The purchaser will respond to such request by publishing the response / clarification in the official websites.

C. PREPARATION OF TENDERS

10. Documents Comprising the Tender

10.1 The Two Bid System, i.e. **"Techno-Commercial Bid"** and **"Financial Bid"** prepared by the tenderer shall comprise the following:

A) <u>Techno-Commercial Bid (Un priced Bid)</u>

i) Earnest money furnished in accordance with GIT clause 18.1 alternatively, documentary evidence as per GIT clause 18.2 for claiming exemption from payment of earnest money.

ii) Tender Form as per Section X (Un-priced).

iii) Documentary evidence, as necessary in terms of GIT clauses 4 and 16 establishing that the tenderer is eligible to submit the tender and, also, qualified to perform the contract if its tender is accepted.

iv) Tenderer/Agent who quotes for goods manufactured by other manufacturer shall furnish Manufacturer's Authorisation Form.

v) Power of attorney in favour of the signatory of the tender document.

vi) Documents and relevant details to establish in accordance with GIT clause 17 that the goods and the allied services to be supplied by the tenderer conform to the requirement of the TE documents.

vii) Performance Statement as per section IX along with relevant copies of orders and end users' satisfaction certificate.

viii) Price Schedule(s) as per Section XI filled up with all the details including Make, Model, etc. of the goods offered with prices blank (without indicating any prices).

ix) Certificate of country of origin by the bidder from abroad. (Chamber of commerce)

x) Checklist as per Section XIX.

xi) IRS and URS (Technical Specification) given as Annexure - I & II, duly filled up and signed and stamped.

xii) Tender fee as mentioned in NIT in the format specified in Clause 6.2 of GIT.

xiii) Copy of PAN Card

xiv) Price Schedule(s) as per Section XI filled up with all the details including Make, Model, etc. of the goods offered with prices blank (without indicating any prices).

B) Financial Bid:

The information given at clause no. 10.1 A) ii) & viii) above should be reproduced with the prices indicated.

10.2 N.B.

1. All pages of the Tender should be page numbered and indexed.
2. It is the responsibility of tenderer to go through the TE document to ensure furnishing all required documents in addition to above, if any.

10.3 The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialled/stamped.

10.4 A tender, which does not fulfil any of the above requirements and/or gives evasive information/reply against any such requirement, shall be liable to be ignored and rejected.

10.5 Tender sent by fax/telex/cable/electronically shall be ignored.

11. Tender currencies

11.1 The tenderer supplying indigenous goods or already imported goods shall quote only in Indian Rupees.

11.2 For imported goods if supplied directly from abroad, prices shall be quoted in any freely convertible currencies say US Dollar, Euro, GBP or Yen. As regards price(s) for allied services, if any required with the goods, the same shall be quoted in Indian Rupees only if such services are to be performed /undertaken in India. Commission for Indian Agent, if any and if payable shall be indicated in the space provided for in the price schedule and will be payable in Indian Rupees only. Such conversion of currencies will be done based on rate of exchange declared by the RBI as on the date of 'Financial Bid' opening as already incorporated against clause 31 here after.

11.3 Tenders, where prices are quoted in any other way shall be treated as non-responsive and rejected.

12. Tender Prices

12.1 The Tenderer shall indicate on the Price Schedule provided under Section XI all the specified components of prices shown therein including the unit prices and total tender prices of the goods and services proposes to supply against the requirement. All the columns shown in the price schedule should be filled up as required. If any column does not apply to a tenderer, same should be clarified as "NA" by the tenderer.

12.2 The price of the schedule complete in all respect will be evaluated and the L1 party will be identified schedule wise.

12.3 The quoted prices for goods offered from within India and that for goods offered from abroad are to be indicated separately in the applicable Price Schedules attached under Section XI.

12.4 While filling up the columns of the Price Schedule, the following aspects should be noted for compliance:

12.4.1 For domestic goods or goods of foreign origin located within India, the prices in the corresponding price schedule shall be entered separately in the following manner:

a) The price of the goods, quoted ex-factory/ ex-showroom/ ex-warehouse/ off-the-shelf, as applicable, including all taxes and duties like sales tax, CST VAT, Custom Duty, Excise Duty etc. already paid or payable on the components and raw material used in the manufacture or assembly of the goods quoted ex-factory etc. or on the previously imported goods of foreign origin quoted ex-showroom etc;

b) Any sales or other taxes and any duties including excise duty, which will be payable on the goods in India if the contract is awarded;

c) Charges towards Packing & Forwarding, Inland Transportation Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule would be borne by supplier;

d) The price of Incidental Services, as mentioned in List of Requirements and Price Schedule;

e) The prices of Turnkey (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and

f) The price of AMC, as mentioned in List of Requirements, Technical Specification and Price Schedule.

12.4.2 For goods offered from abroad, the prices in the corresponding price schedule shall be entered separately in the following manner:

a) The price of goods quoted DAP at Consignee site basis, as indicated in the List of Requirements and Price Schedule;
b) The price of goods quoted should be on DAP at Consignee site basis, in India as indicated in the List of Requirements, Price Schedule and Consignee List;
c) The prices of Turnkey (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and
d) The price for AMC, as mentioned in List of Requirements, Technical Specification and Price Schedule

12.5 For transportation of imported goods offered from abroad, relevant instructions as incorporated under GCC Clause 10 shall be followed.

12.6 For insurance of goods to be supplied, relevant instructions as provided under GCC Clause 11 shall be followed.

12.7 Unless otherwise specifically indicated in the SCC, the terms FOB & DAP for imported goods offered from abroad, shall be governed by the rules & regulations prescribed in the current edition of INCOTERMS, published by the International Chamber of Commerce, Paris.

12.8 The need for indication of all such price components by the tenderers, as required in this clause (viz., GIT clause 12) is for the purpose of comparison of the tenders by the purchaser and will no way restrict the purchaser's right to award the contract on the selected tenderer on any of the terms offered.

13. Indian Agent

13.1 If a foreign tenderer has engaged an agent in India in connection with its tender, the foreign tenderer, in addition to indicating Indian agent's commission, if any, in a manner described under GIT sub clause 11.2 above, shall also furnish the following information:

a) The complete name and address of the Indian Agent and its permanent income tax account number as allotted by the Indian Income Tax authority.

b) The details of the services to be rendered by the agent for the subject requirement.

c) Details of Service outlets in India, nearest to the consignee(s), to render services during Warranty and AMC period.

14. Firm Price

14.1 Unless otherwise specified in the SIT, prices quoted by the tenderer shall remain firm and fixed during the currency of the contract and not subject to variation on any account.

15. Alternative Tenders

15.1 Alternative Tenders are not permitted.

16. Documents Establishing Tenderers Eligibility and Qualifications

16.1 Pursuant to GIT clause 10, the tenderer shall furnish, as part of its tender, relevant details and documents establishing its eligibility to quote and its qualifications to perform the contract if its tender is accepted.

16.2 The documentary evidence needed to establish the tenderer's qualifications shall fulfil the following requirements:

a) In case the tenderer offers to supply goods, which are manufactured by some other firm, the tenderer has been duly authorised by the goods manufacturer to quote for and supply the goods to the purchaser. The tenderer shall submit the manufacturer's authorization letter to this effect as per the standard form provided under Section XIV in this document.

b) The tenderer has the required financial, technical and production capability necessary to perform the contract and, further, it meets the qualification criteria incorporated in the Section IX in these documents.

c) In case, the tenderer is not doing business in India, it is duly represented by an agent stationed in India fully equipped and able to carry out the required contractual functions and duties of the supplier including after sale service, maintenance & repair etc. of the goods in question, stocking of spare parts and fast moving components and other obligations, if any, specified in the conditions of contract and/or technical specifications.

d) In case the tenderer is an Indian agent/authorized representative quoting on behalf of a foreign manufacturer for the **restricted item**, the Indian agent/authorized representative is already enlisted under the Compulsory Enlistment Scheme of Ministry of Finance, Govt. of India, operated through Directorate General of Supplies & Disposals (DGS&D), New Delhi.

17. Documents establishing good's Conformity to Tender Enquiry document.

17.1 The tendered shall provide in its tender the required as well as the relevant documents like technical data, literature, drawings etc. to establish that the goods and services offered in the tender fully conform to the goods and services specified by the purchaser in the TE documents. For this purpose the tendered shall also provide a **clause-by-clause commentary on the technical specifications and other technical details incorporated by the purchaser in the TE Document to establish technical responsiveness of the goods and services offered in its tender.**

17.2 In case there is any variation and/or deviation between the goods & services prescribed by the purchaser and that offered by the tenderer, the tenderer shall list out the same in a chart form without ambiguity and provide the same along with its tender.

17.3 If a tenderer furnishes wrong and/or misguiding data, statement(s) etc. about technical acceptability of the goods and services offered by it, its tender will be liable to be ignored and rejected in addition to other remedies available to the purchaser in this regard.

18. Earnest Money Deposit (EMD)

18.1 Pursuant to GIT clauses 7.1 and 10.1 the tenderer shall furnish along with its tender, earnest money for amount as shown in the NIT). The earnest money is required to protect the purchaser against the risk of the tenderer's unwarranted conduct as amplified under sub-clause 18.7 below. The tenderers who are currently registered and, also, will continue to remain registered during the tender validity period with National Small Industries Corporation (NSIC), New Delhi for the specific goods as per tender enquiry specification are exempted from payment of Bid security (EMD) and other benefits as applicable, but authenticated copy of the valid NSIC certificate for tendered item(s) should be submitted along with Technical bid of the Tender to qualify for such exemptions and other benefits... The EMD should be furnished in the name of "HLL Biotech Limited, payable at Chennai".

18.2 The earnest money shall be denominated in Indian Rupees or equivalent currencies as per GIT clause 11.2. The earnest money shall be furnished in one of the following forms:

Account Payee Demand Draft or Bank Guarantee

18.3 The demand draft shall be drawn on any Scheduled Commercial Bank in India, in favour of "HLL Biotech Limited" payable at Chennai. If the EMD is in the form of bank guarantee, the same is to be provided from any scheduled commercial bank in India or in the case of foreign tenderer, the same should be routed through any scheduled commercial bank as per the format specified under Section XIII of this tender.

18.4 The earnest money shall be valid for a period of forty-five (45) days beyond the validity period of the tender. As validity period of Tender as per Clause 19 of GIT is 120 days, the EMD shall be valid for **165 days** from Techno-Commercial Bid opening date.

18.5 Unsuccessful tenderers' earnest money will be returned to them without any interest, after expiry of the tender validity period, but not later than thirty days after conclusion of the resultant contract. Successful tenderer's earnest money will be returned without any interest, after receipt of performance security from that tenderer.

18.6 Earnest Money is required to protect the purchaser against the risk of the Tenderer's conduct, which would warrant the forfeiture of the EMD. Earnest money of a tenderer will be forfeited, if the tenderer withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged without prejudice to other rights of the purchaser. The successful tenderer's earnest money will be forfeited without prejudice to other rights of Purchaser if it fails to furnish the required performance security within the specified period.

18.7 In the case of Bank Guarantee furnished from banks outside India (i.e. foreign Banks), it should be authenticated and countersigned by any nationalised bank or scheduled bank, but not cooperative banks in India by way of back-to-back counter guarantee.

19. Tender Validity

19.1 If not mentioned otherwise in the SIT, the tenders shall remain valid for acceptance for a period of **120 days (One hundred and twenty days)** from the date of tender opening prescribed in the TE document. Any tender valid for a shorter period shall be treated as unresponsive and rejected.

19.2 In exceptional cases, the tenderers may be requested by the purchaser to extend the validity of their tenders up to a specified period. Such request(s) and responses thereto shall be conveyed by surface mail or by fax/ telex/cable followed by surface mail. The tenderers, who agree to extend the tender validity, are to extend the same without any change or modification of their original tender and they are also to extend the validity period of the EMD accordingly. A tenderer, however, may not agree to extend its tender validity without forfeiting its EMD.

19.3 In case the day up to which the tenders are to remain valid falls on/ subsequently declared a holiday or closed day for the purchaser, the tender validity shall automatically be extended up to the next working day.

20. Signing and Sealing of Tender

20.1 The tenderers shall submit their tenders as per the instructions contained in GIT Clause 10

20.2 The tender shall either be typed or written in indelible ink and the same shall be signed by the tenderer or by a person(s) who has been duly authorized to bind the tenderer to the contract. The letter of authorization shall be by a written power of attorney, which shall also be furnished along with the tender.

20.3 The tender shall be duly signed at the appropriate places as indicated in the TE document and all other pages of the tender including printed literature, if any shall be initialled by the same person(s) signing the tender. The tender shall not contain any erasure or overwriting, except as necessary to correct any error made by the tenderer and, if there is any such correction; the same shall be initialled by the person(s) signing the tender.

20.4 The tenderer should seal the tender and write the address of the purchaser and the tender reference number on the envelope. The sentence “NOT TO BE OPENED before (The tenderer is to put the date & time of tender opening)” are to be written on these envelopes. The inner envelopes are then to be put in a bigger outer envelope, which will also be duly sealed, marked etc. as above. If the outer envelope is not sealed and marked properly as above, the purchaser will not assume any responsibility for its misplacement, premature opening, late opening etc.

20.5 The document seeks quotation following **Two Tender System**, in two parts. First part will be known as ‘**Techno-Commercial Bid**’, and the second part ‘**Financial Bid**’ as specified in clause 10 of GIT. Tenderer shall seal ‘Techno-Commercial Bid’ and ‘Financial Bid’ separately and covers will be suitably super scribed. Both these sealed covers shall be put in a bigger cover and sealed and procedure prescribed in Paras 20.1 to 20.4 followed.

D. SUBMISSION OF TENDERS

21. Submission of Tenders

Unless otherwise specified, the tenders are to be submitted to **The Chief Executive Officer, HLL Biotech Limited, Integrated Vaccine Complex,SF 192-195, Tirumani Village Chengalpattu -600 301**

21.1 The tenderers must ensure that they submit their tenders not later than the closing time and date specified for submission of tenders. It is the responsibility of the tenderer to ensure that their Tenders whether sent by post or by courier or by person, reaches the address mentioned in GIT 21.1 by the specified clearing date and time.

21.2 In the event the specified date for submission of tender falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be received up to the appointed time on the next working day.

22. Late Tender

22.1 A tender, which is received after the specified date and time for receipt of tenders will be treated as "late" tender and will be ignored and not considered.

23. Alteration and Withdrawal of Tender

23.1 The tenderer, after submitting its tender, is permitted to alter / modify its tender so long as such alterations / modifications are received duly signed, sealed and marked like the original tender, within the deadline for submission of tenders. Alterations / modifications to tenders received after the prescribed deadline will not be considered.

23.2 No tender should be withdrawn after the deadline for submission of tender and before expiry of the tender validity period. If a tenderer withdraws the tender during this period, it will result in forfeiture of the earnest money furnished by the tenderer in its tender.

E. TENDER OPENING

24. Opening of Tenders

24.1 The purchaser will open the tenders at the specified date and time and at the specified place as indicated in the NIT. In case the specified date of tender opening falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be opened at the appointed time and place on the next working day.

24.2 Authorized representatives of the tenderers, who have submitted tenders on time, may attend the tender opening, provided they bring with them letters of authority from the corresponding tenderers.
The tender opening official(s) will prepare a list of the representatives attending the tender opening. The list will contain the representatives' names & signatures and corresponding tenderers' names and addresses.

24.3 Two - Tender system as mentioned in para 20.5 above will be as follows. The Techno-Commercial Bids are to be opened in the first instance, at the prescribed time and date as indicated in NIT. These Tenders shall be scrutinized and evaluated by the competent committee/ authority with reference to parameters prescribed in the TE document. During the Techno-Commercial Bid opening, the tender opening official(s) will read the salient features of the tenders like brief description of the goods offered, delivery period, Earnest Money Deposit and any other special features of the tenders, as deemed fit by the tender opening official(s). Thereafter, in the second stage, the Financial Bid of only the Technically qualified offers (as decided in the first stage) shall be opened for further scrutiny and evaluation on a date notified after the evaluation of the Techno-Commercial Bid. The prices, special discount if any of the goods offered etc., as deemed fit by tender opening official(s) will be read out.

F. SCRUTINY AND EVALUATION OF TENDERS

25. Basic Principle

25.1 Tenders will be evaluated on the basis of the terms & conditions already incorporated in the TE document, based on which tenders have been received and the terms, conditions etc. mentioned by the tenderers in their tenders. No new condition will be brought in while scrutinizing and evaluating the tenders.

26. Preliminary Scrutiny of Tenders

26.1 The Purchaser will examine the Tenders to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed stamped and whether the Tenders are generally in order.

26.2 Prior to the detailed evaluation of Financial Bid, pursuant to GIT Clause 33, the Purchaser will determine the substantial responsiveness of each Tender to the TE Document. For purposes of these clauses, a substantially responsive Tender is one, which conforms to all the terms and conditions of the TE Document without material deviations. Deviations from, or objections or reservations to critical provisions such as those concerning Performance Security (GCC Clause 5), Warranty (GCC Clause 15), EMD (GIT Clause 18), Taxes & Duties (GCC Clause 20), Force Majeure (GCC Clause 26) and Applicable law (GCC Clause 31) will be deemed to be a material deviation. The Purchaser's determination of a Tender's responsiveness is to be based on the contents of the tender itself without recourse to extrinsic evidence.

26.3 If a Tender is not substantially responsive (Non-Responsive), it will be rejected by the Purchaser and cannot subsequently be made responsive by the Tenderer by correction of the nonconformity.

26.4 The tenders will be scrutinized to determine whether they are complete and meet the essential and important requirements, conditions etc. as prescribed in the TE document. The tenders, which do not meet the basic requirements, are liable to be treated as non – responsive and will be summarily ignored. A non-responsive tender is one which deviates technically or commercially from any specific provision in the tender enquiry.

26.5 The following are some of the important aspects, for which a tender shall be declared non – responsive and will be summarily ignored:

(i) Tender form as per Section X (signed and stamped) not enclosed
(ii) Tender is unsigned.
(iii) Tender validity is shorter than the required period.
(iv) Required EMD (Amount, validity etc.) / exemption documents have not been provided.
(v) Tenderer has quoted for goods manufactured by other manufacturer(s) without the required Manufacturer's Authorisation Form as per Section XIV.
(vi) Tenderer has not agreed to give the required performance security.
(vii) Goods offered are not meeting the tender enquiry specification.
(viii) Tenderer has not agreed to other essential condition(s) specially incorporated in the tender enquiry like terms of payment, liquidated damages clause, warranty clause, dispute resolution mechanism applicable law.
(ix) Poor/ unsatisfactory past performance.
(x) Tenderers who stand deregistered/banned/blacklisted by any Govt. Authorities.
(xi) Tenderer is not eligible as per GIT Clauses 4.1 & 16.1.
(xii) Tenderer has not quoted for the entire quantity as specified in the List of Requirements in the quoted schedule.
(xiii) The signed Integrity Pact not enclosed by the Tenderer.
(xiv) IRS and URS / Datasheet given in Annexure-I, & II / Annexures, not duly filled, signed and stamped.

27. Minor Infirmity /Irregularity/Non-Conformity

27.1 If during the preliminary examination, the purchaser find any minor informality and/or irregularity and/or non-conformity in a tender, the purchaser may waive the same provided it does not constitute any material deviation and financial impact and, also, does not prejudice or affect the ranking order of the tenderers. Wherever necessary, the purchaser will convey its observation on such 'minor' issues to the tenderer, asking

the tenderer to respond by a specified date. If the tenderer does not reply by the specified date or gives evasive reply without clarifying the point at issue in clear terms, that tender will be liable to be ignored.

28. Discrepancies in Prices

28.1 If, in the price structure quoted by a tenderer, there is discrepancy between the unit price and the total price (which is obtained by multiplying the unit price by the quantity), the unit price shall prevail and the total price corrected accordingly, unless the purchaser feels that the tenderer has made a mistake in placing the decimal point in the unit price, in which case the total price as quoted shall prevail over the unit price and the unit price corrected accordingly.

28.2 If there is an error in a total price, which has been worked out through addition and/or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected accordingly; and

28.3 If there is a discrepancy between the amount expressed in words and figures, the amount in words shall prevail, subject to sub clause 28.1 and 28.2 above.

28.4 If, as per the judgement of the purchaser, there is any such arithmetical discrepancy in a tender, the same will be suitably conveyed to the tenderer by registered / speed post. If the tenderer does not agree to the observation of the purchaser, the tender is liable to be ignored.

29. Discrepancy between original and copies of Tender

29.1 In case, any discrepancy is observed between the text etc. of the original copy and that in the other copies of the same tender set, the text etc. of the original copy shall prevail. Here also, the purchaser will convey its observation suitably to the tenderer by register / speed post and, if the tenderer does not accept the purchaser's observation, that tender will be liable to be ignored.

30. Qualification Criteria

30.1 Tenders of the tenderers, who do not meet the required Qualification Criteria prescribed in Section IX, will be treated as non - responsive and will not be considered further.

31. Conversion of tender currencies to Indian Rupees

31.1 In case the TE document permits the tenderers to quote their prices in different currencies, all such quoted prices of the responsive tenderers will be converted to a single currency viz., Indian Rupees for the purpose of equitable comparison and evaluation, as per the exchange rates established by the Reserve Bank of India for similar transactions, as on the date of 'Financial Bid' opening.

32. Schedule/ Package -wise Evaluation

32.1 In case the List of Requirements contains more than one schedule/ Package, the responsive tenders will be evaluated and compared separately for each schedule/package. The tender for a schedule/ package will not be considered if the complete requirements prescribed in that schedule/ package are not included in the tender. However, as already mentioned in GIT sub clause 12.2, the tenderers have the option to quote for any one or more schedules/ package.

33. Comparison of Tenders

33.1 Unless mentioned otherwise in Section – III – Special Instructions to Tenderers and Section – VI – List of Requirements, the comparison of the responsive tenders shall be carried out on Delivery Duty Paid (DDP) consignee site basis. The quoted turnkey (if any) prices and AMC prices will also be added for comparison/ranking purpose for evaluation.

34. Additional Factors and Parameters for Evaluation and Ranking of Responsive Tenders

34.1 Deleted

34.2 The purchaser's evaluation of tender will also take into account the additional factors, if any, incorporated in SIT in the manner and to the extent indicated therein.

34.3 The Purchaser reserves the right to give the price preference to small-scale sectors etc. and purchase preference to central public sector undertakings as per the instruction in vogue while evaluating, comparing and ranking the responsive tenders.

35. Tenderer's capability to perform the contract

35.1 The purchaser, through the above process of tender scrutiny and tender evaluation will determine to its satisfaction whether the tenderer, whose tender has been determined as the lowest evaluated responsive tender is eligible, qualified and capable in all respects to perform the contract satisfactorily. If, there is more than one schedule/ package in the List of Requirements, then, such determination will be made separately for each schedule/ package.

35.2 The above-mentioned determinations will, interalia, take into account the tenderer's financial, technical and production capabilities for satisfying all the requirements of the purchaser as incorporated in the TE document. Such determination will be based upon scrutiny and examination of all relevant data and details submitted by the tenderer in its tender as well as such other allied information as deemed appropriate by the purchaser.

36. Contacting the Purchaser

36.1 From the time of submission of tender to the time of awarding the contract, if a tenderer needs to contact the purchaser for any reason relating to this tender enquiry and / or its tender, it should do so only in writing.

36.2 In case a tenderer attempts to influence the purchaser in the purchaser's decision on scrutiny, comparison & evaluation of tenders and awarding the contract, the tender of the tenderer shall be liable for rejection in addition to appropriate administrative actions being taken against that tenderer, as deemed fit by the purchaser.

G. AWARD OF CONTRACT

37. Purchaser's Right to accept any tender and to reject any or all tenders

37.1 The purchaser reserves the right to accept in part or in full any tender or reject any or more tender(s) without assigning any reason or to cancel the tendering process and reject all tenders at any time prior to award of contract, without incurring any liability, whatsoever to the affected tenderer or tenderers.

38. Award Criteria

38.1 Subject to GIT clause 37 above, the contract will be awarded to the lowest evaluated responsive tenderer decided by the purchaser in terms of GIT Clause 35.

39. Variation of Quantities at the Time of Award/ Currency of Contract

39.1 At the time of awarding the contract, the purchaser reserves the right to increase or decrease by up to fifty (50) per cent, the quantity of goods and services mentioned in the schedule (s) in the "List of Requirements" (rounded off to next whole number) without any change in the unit price and other terms & conditions quoted by the tenderer.

39.2 If the quantity has not been increased at the time of the awarding the contract, the purchaser reserves the right to increase by up to fifty (50) per cent, the quantity of goods and services mentioned in the contract (rounded off to next whole number) without any change in the unit price and other terms & conditions mentioned in the contract, during the currency of the contract after one year from the Date of Notification of Award.

40. Notification of Award

40.1 Before expiry of the tender validity period, the purchaser will notify the successful tenderer(s) in writing, by registered / speed post/ courier or by fax/telex/cable (to be confirmed by registered / speed post/courier) that its tender for goods & services, which have been selected by the purchaser, has been accepted, also briefly indicating therein the essential details like description, specification and quantity of the goods & services and corresponding prices accepted. The successful tenderer must furnish to the purchaser the required performance security within thirty days from the date of dispatch of this notification, failing which the EMD will forfeited and the award will be cancelled. Relevant details about the performance security have been provided under GCC Clause 5 under Section IV.

40.2 The Notification of Award shall constitute the conclusion of the Contract.

41. Issue of Contract

41.1 Promptly after notification of award, the Purchaser/Consignee will mail the contract form (as per Section XVI) duly completed and signed, in duplicate, to the successful tenderer by registered / speed post/courier.

41.2 Within twenty one days from the date of the contract, the successful tenderer shall return the original copy of the contract, duly signed and dated, to the Purchaser by registered / speed post/courier.

41.3 The Purchaser- reserves the right to issue the Notification of Award consignee wise.

42. Non-receipt of Performance Security and Contract by the Purchaser/Consignee

42.1 Failure of the successful tenderer in providing performance security and / or returning contract copy duly signed in terms of GIT clauses 40 and 41 above shall make the tenderer liable for forfeiture of its EMD and, also, for further actions by the Purchaser/Consignee against it as per the clause 24 of GCC – Termination of default.

43. Return of E M D

43.1 The earnest money of the successful tenderer and the unsuccessful tenderers will be returned to them without any interest, whatsoever, in terms of GIT Clause 18.7

44. Publication of Tender Result

44.1 The name and address of the successful tenderer(s) receiving the contract(s) will be mentioned in the notice board/bulletin/web site of the purchaser.

45. Corrupt or Fraudulent Practices

45.1 It is required by all concerned namely the Consignee/Tenderers/Suppliers etc to observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the Purchaser: -

(a) defines, for the purposes of this provision, the terms set forth below as follows:

(i) "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and

(ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after Tender submission) designed to establish Tender prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition;

(b) will reject a proposal for award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;

(c) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a contract by the purchaser if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing the contract.

46. Integrity Pact (IP)

The Integrity Pact (IP) will be one of the conditions in this tender enquiry. It will be considered to be a material deviation resulting into ignoring and rejecting the tender if the tenderers do not agree to accept it. The detailed terms of the IP are given below:

The Public Authority commits that:

- No official will demand or accept any illicit gratification to give any of the parties an advantage at any stage of the project.
- All necessary and appropriate technical, legal and administrative information related to the contract will be made public
- None of the officials will make available confidential information to a bidder/contractor to give unfair advantage in the contract
- Declaration by all concerned officials any conflict of interest and disclosure of own and family assets
- Officials will report to appropriate government authority about any breach/attempt to breach a commitment.

The Bidder commits that:

- they will not offer any illicit gratification to obtain unfair advantage
- they will not collude with other parties to impair transparency and fairness

- they will not accept any advantage in exchange for unprofessional behaviour
- will disclose all payments made to agents and intermediaries
- it will demonstrate existence of organization-wide code of conduct forbidding unethical practices

Penalties:

For failure to implement IP, officials will be subject to penal action and bidders will face cancellation of contract, forfeiture of bond, liquidated damages and blacklisting. Action will not require criminal conviction but be based on "no-contest" after the evidence is made available or there can be no material doubts. Disputes in IP implementation would be resolved by arbitration detailed in IP.

Integrity Pact has to be signed and submitted by the Tenderer along with the filled up Tenders, failing which the Tender is liable to be rejected. Integrity Pact is enclosed in Section-XXI

47. Paying Authority:

47.1 The payment for the supplies of stores / goods / equipments which including agency commission, turnkey (if any), installation and commissioning and any other payment mentioned in the tender enquiry will be made by "**HLL Biotech Limited**".

SECTION - III

SPECIAL INSTRUCTIONS TO TENDERERS (SIT)

Sl. No.	GIT Clause No.	Topic	SIT Provision
A	1 to 6	Preamble	No Change
B	7 to 9	TE documents	No Change
C	10 to 20	Preparation of Tenders	No Change
D	21 to 23	Submission of Tenders	No Change
E	24	Tender Opening	No Change
F	25 to 33, 35,36	Scrutiny and Evaluation of Tenders	No Change
G	37 to 47	Award of Contract	No Change

In case of any conflict between the provision in the GIT and that in the SIT, the provision contained in the SIT shall prevail.

MSE units who are registered and also will continue to remain registered during the tender validity period with NSIC are exempted from payment of Bid security (EMD) and other benefits as applicable, but authenticated copy of the valid NSIC certificate for tendered item(s) should be submitted along with Techno-Commercial Bid of the Tender to qualify for such exemptions and other benefits.

SECTION – IV

GENERAL CONDITIONS OF CONTRACT (GCC)

TABLE OF CLAUSES

SECTION - IV

GENERAL CONDITIONS OF CONTRACT (GCC)

1. Application

1.1 The General Conditions of Contract incorporated in this section shall be applicable for this purchase to the extent the same are not superseded by the Special Conditions of Contract prescribed under Section V, List of requirements under Section VI and Technical Specification under Section VII of this document.

2. Use of contract documents and information

2.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract or any provision thereof including any specification, drawing, sample or any information furnished by or on behalf of the purchaser in connection therewith, to any person other than the person(s) employed by the supplier in the performance of the contract emanating from this TE document. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for the purposes of such performance for this contract.

2.2 Further, the supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC sub-clause 2.1 above except for the sole purpose of performing this contract.

2.3 Except the contract issued to the supplier, each and every other document mentioned in GCC sub-clause 2.1 above shall remain the property of the purchaser and, if advised by the purchaser, all copies of all such documents shall be returned to the purchaser on completion of the supplier's performance and obligations under this contract.

3. Patent Rights

3.1 The supplier shall, at all times, indemnify and keep indemnified the purchaser, free of cost, against all claims which may arise in respect of goods & services to be provided by the supplier under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks. In the event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against the purchaser, the purchaser shall notify the supplier of the same and the supplier shall, at his own expenses take care of the same for settlement without any liability to the purchaser.

4. Country of Origin

4.1 All goods and services to be supplied and provided for the contract shall have the origin in India or in the countries with which the Government of India has trade relations.

4.2 The word "origin" incorporated in this clause means the place from where the goods are mined, cultivated, grown, manufactured, produced or processed or from where the services are arranged.

4.3 The country of origin may be specified in the Price Schedule

5. Performance Security

5.1 Within **ten (10) days** from date of the issue of notification of award by the Purchaser/Consignee, the supplier, shall furnish performance security to the Purchaser/Consignee for an amount equal to **five percent (5%)** of the total value of the contract, valid up to sixty (60) days after the date of completion of all contractual

obligations by the supplier, including the warranty obligations, initially valid for a period of **minimum 18 months** from the date of Notification of Award

5.2 The Performance security shall be denominated in Indian Rupees or in the currency of the contract as detailed below:

a) It shall be in the form of Bank Guarantee issued by a Scheduled Commercial bank in India or in the case of a foreign tenderer, the same shall be routed through a Nationalised Indian Bank, in the prescribed form as provided in section XV of this document in favour of the Purchaser. The validity of the Fixed Deposit receipt or Bank Guarantee will be for a period up to sixty (60) days beyond Warranty Period.

5.3 In the event of any failure /default of the supplier with or without any quantifiable loss to the government including furnishing of Bank Guarantee for AMC Security as per Proforma in Section XV, the amount of the performance security is liable to be forfeited.

5.4 In the event of any amendment issued to the contract, the supplier shall, within twenty-one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary), rendering the same valid in all respects in terms of the contract, as amended.

5.5 The supplier shall enter into AMC as per the 'Contract Form – B' in Section XVI with the Consignee/Purchaser, 3 (three) months prior to the completion of Warranty Period. The AMC will commence from the date of expiry of the Warranty Period.

5.6 Subject to GCC sub – clause 5.3 above, the Purchaser/Consignee will release the Performance Security without any interest to the supplier on completion of the supplier's all contractual obligations including the warranty obligations & after receipt of Consignee wise (in the case of more than one consignee) bank guarantee for AMC Security in favour of the consignee as per the format in Section XV.

6. Technical Specifications and Standards

6.1 The Goods & Services to be provided by the supplier under this contract shall conform to the technical specifications and quality control parameters mentioned in 'Technical Specification'; 'Quality Control Requirements' under Sections VII and Section VIII of this document and URS enclosed as annexure to this document.

7. Packing and Marking

7.1 The packing for the goods to be provided by the supplier should be strong and durable enough to withstand, without limitation, the entire journey during transit including transhipment (if any), rough handling, open storage etc. without any damage, deterioration etc. As and if necessary, the size, weights and volumes of the packing cases shall also take into consideration, the remoteness of the final destination of the goods and availability or otherwise of transport and handling facilities at all points during transit up to final destination as per the contract.

7.2 The quality of packing, the manner of marking within & outside the packages and provision of accompanying documentation shall strictly comply with the requirements as provided in Technical Specifications and Quality Control Requirements under Sections VII and VIII and in SCC under Section V. In case the packing requirements are amended due to issue of any amendment to the contract, the same shall also be taken care of by the supplier accordingly.

7.3 Packing instructions:

Unless otherwise mentioned in the Technical Specification and Quality Control Requirements under Sections VII and Section VIII and in SCC under Section V, the supplier shall make separate packages for each consignee (in case there is more than one consignee mentioned in the contract) and mark each package on three sides with the following with indelible paint of proper quality:

a. contract number and date
b. brief description of goods including quantity
c. packing list reference number
d. country of origin of goods
e. consignee's name and full address and
f. supplier's name and address

8. Inspection, Testing and Quality Control

8.1 The purchaser and/or its nominated representative(s) will, without any extra cost to the purchaser, inspect and/or test (FAT) the ordered goods and the related services to confirm their conformity to the contract specifications and other quality control details incorporated in the contract. The purchaser shall inform the supplier in advance, in writing, the purchaser's programme for such inspection (FAT) and, also the identity of the officials to be deputed for this purpose. The cost towards the transportation, boarding & lodging will be borne by the purchaser and/or its nominated representative(s).

8.2 The Technical Specification and Quality Control Requirements incorporated in the contract / URS shall specify what inspections and tests are to be carried out and, also, where and how they are to be conducted. If such inspections and tests are conducted in the premises of the supplier or its subcontractor(s), all reasonable facilities and assistance, including access to relevant drawings, design details and production data, shall be furnished by the supplier to the purchaser's inspector at no charge to the purchaser.

8.3 If during such inspections (FAT) and tests the contracted goods fail to conform to the required specifications and standards, the purchaser's inspector may reject them and the supplier shall either replace the rejected goods or make all alterations necessary to meet the specifications and standards, as required, free of cost to the purchaser and resubmit the same for conducting the inspections and tests again.

8.4 In case the contract stipulates pre-despatch inspection of the ordered goods at supplier's premises, the supplier shall put up the goods for such inspection to the purchaser's inspector well ahead of the contractual delivery period, so that the purchaser's inspector is able to complete the inspection within the contractual delivery period.

8.5 If the supplier tenders the goods to the purchaser's inspector for inspection at the last moment without providing reasonable time to the inspector for completing the inspection within the contractual delivery period, the inspector may carry out the inspection and complete the formality beyond the contractual delivery period at the risk and expense of the supplier. The fact that the goods have been inspected after the contractual delivery period will not have the effect of keeping the contract alive and this will be without any prejudice to the legal rights and remedies available to the purchaser under the terms & conditions of the contract.

8.6 The purchaser's/consignee's contractual right to inspect, test and, if necessary, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by purchaser's inspector during pre-despatch inspection mentioned above.

8.7 Goods accepted by the purchaser/consignee and/or its inspector at initial inspection and in final inspection in terms of the contract shall in no way dilute purchaser's/consignee's right to reject the same later, if found deficient in terms of the warranty clause of the contract, as incorporated under GCC Clause 15.

8.8 If stipulated by the Purchaser, the Principal/ Foreign or Domestic suppliers shall also have the equipment inspected by recognised/ reputed agency like SGS, Lloyd or equivalent (acceptable to the purchaser) prior to despatch at the supplier's cost and furnish necessary certificate from the said agency in support of their claim.

9. Terms of Delivery

9.1 Goods shall be delivered by the supplier in accordance with the terms of delivery specified in the **Schedule of Fiscal Aspects**.

10. Transportation of Goods

10.1 Instructions for transportation of imported goods offered from abroad:

The supplier shall not make part-shipments and/or transhipment without the express/prior written consent of the purchaser. The supplier is required under the contract to deliver the goods under DAP at consignee site basis.

10.2 Transportation of domestic goods including goods already imported by the supplier to be done by the supplier himself and the goods to be delivered at the site of the consignee at his own cost.

11. Insurance:

Unless otherwise instructed in the SCC, the supplier shall make arrangements for insuring the goods against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery.

The supplier shall be responsible till the entire stores contracted for arrival in good condition at destination. The transit risk in this respect shall be covered by the Supplier by getting the stores duly insured. The insurance cover shall be obtained by the Supplier and should be valid till 3 months after the receipt of goods by the consignee.

If the equipment is not commissioned and handed over to the consignee within 3 months, the insurance will be extended by the supplier at their own cost till the successful installation, testing, commissioning and handing over of the goods to the consignee. In case the delay in the installation and commissioning is due to handing over of the site to the supplier by the consignee, such extensions of the insurance will still be done by the supplier, but the insurance extension charges at actuals will be reimbursed.

12. Spare parts

12.1 If specified in the List of Requirements and in the resultant contract, the supplier shall supply/provide any or all of the following materials, information etc. pertaining to spare parts manufactured and/or supplied by the supplier:

a) The spare parts as selected by the Purchaser/Consignee to be purchased from the supplier, subject to the condition that such purchase of the spare parts shall not relieve the supplier of any contractual obligation including warranty obligations; and

b) In case the production of the spare parts is discontinued:

i. Sufficient advance notice to the Purchaser/Consignee before such discontinuation to provide adequate time to the purchaser to purchase the required spare parts etc., and
ii. Immediately following such discontinuation, providing the Purchaser/Consignee, free of cost, the designs, drawings, layouts and specifications of the spare parts, as and if requested by the Purchaser/Consignee.

12.2 Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spares for the goods so that the same are supplied to the Purchaser/Consignee promptly on receipt of order from the Purchaser/Consignee.

13. Incidental services

13.1 Subject to the stipulation, if any, in the SCC (Section – V), List of Requirements (Section – VI) and the Technical Specification (Section – VII), the supplier shall be required to perform the following services.

i. Installation & commissioning, Supervision and Demonstration of the goods
ii. Providing required jigs and tools for assembly, minor civil works required for the Completion of the installation.

iii. Training of Consignee for operating and maintaining the goods
iv. Supplying required number of operation & maintenance manual for the goods

14. Distribution of Dispatch Documents for Clearance/Receipt of Goods

The supplier shall send all the relevant despatch documents well in time to the Purchaser / Consignee to enable the Purchaser/Consignee clear or receive (as the case may be) the goods in terms of the contract. Unless otherwise specified in the SCC, the usual documents involved and the drill to be followed in general for this purpose are as follows.

A) For Domestic Goods, including goods already imported by the supplier under its own arrangement

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract):

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
(ii) Two copies of packing list identifying contents of each package;
(iii) Inspection certificate issued by the nominated Inspection agency, if any.
(iv) Certificate of origin;
(v) Manufacturers/Supplier's warranty certificate & In-house inspection certificate.

B) For goods imported from abroad

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract).

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Original and four copies of the negotiable clean, on-board Bill of Lading/Airway bill, marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;

(iii) Four Copies of packing list identifying contents of each package;

(iv) Manufacturer's/Supplier's warranty certificate

(v) Certificate of origin

(vi) Port of Loading;

(vii) Port of Discharge and

(viii) Expected date of arrival.

15. Warranty

15.1 The supplier warrants comprehensively that the goods supplied under the contract is new, unused and incorporate all recent improvements in design and materials unless prescribed otherwise by the purchaser in the contract. The supplier further warrants that the goods supplied under the contract shall have no defect arising from design, materials (except when the design adopted and / or the material used are as per the Purchaser's/Consignee's specifications) or workmanship or from any act or omission of the supplier, that may develop under normal use of the supplied goods under the conditions prevailing in India.

15.2 This warranty shall remain valid for **1 (one) year** after the goods or any portion thereof as the case may be, have been delivered to the final destination and installed and commissioned at the final destination and accepted by the Purchaser/Consignee in terms of the contract, unless specified otherwise in the SCC.

a. No conditional warranty will be acceptable.

b. Warranty as well as AMC will be inclusive of all accessories and Turnkey (if any) work and it will also cover all wearable & non wearable components.

c. Replacement and repair will be under taken for the defective goods.

d. Proper marking has to be made for all spares for identification like printing of installation and repair dates.

15.3 In case of any claim arising out of this warranty, the Purchaser/Consignee shall promptly notify the same in writing to the supplier. The period of the warranty will be as per G.C.C clause number 15.2 above irrespective of any other period mentioned elsewhere in the bidding documents.

15.4 Upon receipt of such notice, the supplier shall, within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis respond to take action and initiate to repair or replace the defective goods or parts thereof, free of cost, at the ultimate destination within 48 hours. The supplier shall take over the replaced parts/goods after providing their replacements and no claim, whatsoever shall lie on the purchaser for such replaced parts/goods thereafter. The penalty clause for non-rectification will be applicable as per tender conditions.

15.5 In the event of any rectification of a defect or replacement of any defective goods during the warranty period, the warranty for the rectified/replaced goods shall be extended to a further initial warranty period from the date such rectified / replaced goods starts functioning to the satisfaction of the purchaser.

15.6 If the supplier, having been notified, fails to respond to take action to repair or replace the defect(s) within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis, the purchaser may proceed to take such remedial action(s) as deemed fit by the purchaser, at the risk and expense of the supplier and without prejudice to other contractual rights and remedies, which the purchaser may have against the supplier.

15.7 During Warranty period, the supplier is required to visit consignee's site at least once in 3 months commencing from the date of the installation for preventive maintenance of the goods.

15.8 The Purchaser/Consignee reserve the rights to enter into AMC with the Supplier for the period as mentioned in Section VII, Technical Specifications after the completion of warranty period.

15.9 The supplier along with its Indian Agent and the Service Provider shall ensure continued supply of the spare parts for the machines and equipment's supplied by them to the purchaser for 10 years from the date of installation and handing over.

15.10 The Supplier along with its Indian Agent and the Service Provider shall always accord most favoured purchaser status vis-à-vis its other /Purchasers of its equipment's/machines/goods etc. and shall always give the most competitive price for its machines/equipment's supplied to the Purchaser/Consignee.

16. Assignment

16.1 The Supplier shall not assign, either in whole or in part, its contractual duties, responsibilities and obligations to perform the contract, except with the Purchaser's prior written permission.

17. Sub Contracts

17.1 The Supplier shall notify the Purchaser in writing of all sub contracts awarded under the contract if not already specified in its tender. Such notification, in its original tender or later, shall not relieve the Supplier from any of its liability or obligation under the terms and conditions of the contract.

17.2 Sub contract shall be only for bought out items and sub-assemblies.

17.3 Sub contracts shall also comply with the provisions of GCC Clause 4 ("Country of Origin").

18. Modification of contract

18.1 If necessary, the purchaser may, by a written order given to the supplier at any time during the currency of the contract, amend the contract by making alterations and modifications within the general scope of contract in any one or more of the following:

a) Specifications, drawings, designs etc. where goods to be supplied under the contract are to be specially manufactured for the purchaser,

b) Mode of packing,

c) Incidental services to be provided by the supplier

d) Mode of despatch,

e) Place of delivery, and

f) Any other area(s) of the contract, as felt necessary by the purchaser depending on the merits of the case.

18.2 In the event of any such modification/alteration causing increase or decrease in the cost of goods and services to be supplied and provided, or in the time required by the supplier to perform any obligation under the contract, an equitable adjustment shall be made in the contract price and/or contract delivery schedule, as the case may be, and the contract amended accordingly. If the supplier doesn't agree to the adjustment made by the Purchaser/Consignee, the supplier shall convey its views to the Purchaser/Consignee within

twenty-one days from the date of the supplier's receipt of the Purchaser's/Consignee's amendment / modification of the contract.

19. Prices

19.1 Prices to be charged by the supplier for supply of goods and provision of services in terms of the contract shall not vary from the corresponding prices quoted by the supplier in its tender.

20. Taxes and Duties

20.1 Supplier shall be entirely responsible for all taxes, duties, fees, levies etc. incurred until delivery of the contracted goods to the purchaser.

20.2 Further instruction, if any, shall be as provided in the SCC.

20.3 No exemption certificate will be provided by the consignees for customs duty, central Excise duty etc.

20.4 HBL will issue a 'C' form for interstate sale.

20.5 The entry tax, if applicable, the exemption certificate will be issued.

21. Terms and Mode of Payment

21.1 Payment Terms

Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of contract in the following manner.

A) Payment for Domestic Goods Or Foreign Origin Located Within India.

Payment shall be made in Indian Rupees as specified in the contract in the following manner:

a) Advance

An advance of 10% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 5 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) On delivery at site:

70 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;

(iii) Two copies of packing list identifying contents of each package;

(iv) Dispatch Clearance from Purchaser or authorized agent

(v) Inspection certificate issued by the nominated Inspection agency, if any.

(vi) Certificate of Country of origin.

c) On Installation Operational Qualification (IOQ) & submission of IOQ report approved by purchaser:

10% of the Contract Value

d) On validation and Final Acceptance Certificate approved by Purchaser:

Balance 10% payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

B) Payment for Imported Goods:

100% of the Payment shall be made in the currency through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the supplier in a bank in his country as specified in the contract in the following manner:

a) Advance

10% of the net DAP price after submission of Bank guarantee equivalent to 110% of the advance amount in the same currency along with submission of Security Deposit / Performance security equal to 5% of the contract value in the form of a bank guarantee from or in the case of a foreign tenderer, the same shall be endorsed by a Nationalized Indian Bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

b) On Receipt of Goods at site:

70% of the net DAP price (DAP price less Indian Agency commission) of the goods delivered shall be paid and upon submission of documents specified hereunder:

(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;

(ii) Original and four copies of the negotiable clean, on-board Bill of Lading/ Airway bill , marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;

(iii) Four Copies of packing list identifying contents of each package;

(iv) Documents also to be submitted for payment of LC confirming that dispatch documents has already been sent to all concerned as per the contract within 24 hours;

(v) Manufacturer's/Supplier's warranty certificate;

(vi) Manufacturer's own factory inspection report and

(vii) Certificate of origin by the chamber of commerce of the concerned country;

(viii) Goods receipt certificate by the ultimate consignee on receipt of goods at this site/warehouse as per section XVII of this tender document.

c) On Installation Operational Qualification (IOQ) & submission of IOQ report approved by purchaser

10% of the net DAP price

d) On validation and Final Acceptance Certificate approved by Purchaser:

Balance 10 % of the net DAP price payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

e) Payment of **incidental services (including installation & commissioning, supervision, demonstration and training)** will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative or to the principal in their currency.

f) Payment of customs clearance and handling charges, loading/ unloading, inland transportation, incidental costs till consignee site will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative or to the principal in their currency on intimation to the purchaser with Bill of Entry and supporting documents. However Customs duty will be paid in Indian Rupees to the customs department directly by HBL on intimation by the vendor's Customs Clearing Agent with demand notice / Assessment order from Customs.

g) Payment of Indian Agency Commission:

Indian Agency commission will be paid to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule (as per prevailing rate of exchange ruling on the date of Contract) and shall not be subject to further escalation / exchange variation. 100% Payment shall be paid in Indian Rupees to the Indian Agent after 100 % payment to the foreign principal.

h) Payment for services:

In case of separate service order issued to the vendor, the payment terms shall be as below:

a) 50% of service order value against installation
b) 30% of service order value against commissioning
c) Balance 20% of service order value against Final Acceptance Certificate by Purchaser

C) Payment of Turnkey (if any) (For Supply, Installation, Commissioning and Validation of Lab equipment (Phase-IV):

Turnkey (if any) payment will be made to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule.

Payment of Turnkey (if any) shall be made in the following stages:

d) 50% against installation
e) 30% against commissioning
f) Balance 20% against Final Acceptance Certificate by Purchaser.

D) Payment for AMC Charges:

The Consignee/Client will enter into AMC with the supplier at the rates as stipulated in the contract, three months prior to completion of warranty period. The payment of AMC will be made on half yearly basis after satisfactory completion of said period, duly certified by the consignee.

However entering into an agreement on AMC Service with the Supplier on completion of warranty period is the sole discretion of the Purchaser.

21.2 The supplier shall not claim any interest on payments under the contract.

21.3 Where there is a statutory requirement for tax deduction at source, such deduction towards income tax and other tax as applicable will be made from the bills payable to the Supplier at rates as notified from time to time.

21.4 Irrevocable & non – transferable LC shall be opened by the Purchaser. However, if the supplier requests specifically to open confirmed LC, the extra charges would be borne by the supplier. If LC is required to be extended and/or amended for reasons not attributable to the purchaser/consignee, the charges thereof shall be borne by the supplier.

21.5 The payment shall be made in the currency / currencies authorised in the contract.

21.6 The supplier shall send its claim for payment in writing, when contractually due, along with relevant documents etc., duly signed with date, to the purchaser.

21.7 While claiming payment, the supplier has also to certify in the bill that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the supplier for claiming that payment has been fulfilled as required under the contract.

21.8 In case where the supplier is not in a position to submit its bill for the balance payment for want of receipted copies of Inspection Note from the consignee and the consignee has not complained about the non-receipt, shortage, or defects in the supplies made, balance amount will be paid by the paying authority without consignee's receipt certificate after three months from the date of the preceding part payment for the goods in question, subject to the following conditions:

(a) The supplier will make good any defect or deficiency that the consignee (s) may report within six months from the date of despatch of goods.
(b) Delay in supplies, if any, has been regularized.
(c) The contract price where it is subject to variation has been finalized.
(d) The supplier furnishes the following undertakings:

"I/We, _____ certify that I/We have not received back the Inspection Note duly receipted by the consignee or any communication from the purchaser or the consignee about non-receipt, shortage or defects in the goods supplied. I/We _____ agree to make good any defect or deficiency that the consignee may report within three months from the date of receipt of this balance payment.

22. Delay in the supplier's performance

22.1 The supplier shall deliver of the goods and perform the services under the contract within the time schedule specified by the Purchaser/Consignee in the List of Requirements and as incorporated in the contract.

22.2 Subject to the provision under GCC clause 26, any unexcused delay by the supplier in maintaining its contractual obligations towards delivery of goods and performance of services shall render the supplier liable to any or all of the following sanctions:

(i) Imposition of liquidated damages,

(ii) Forfeiture of its performance security and

(iii) Termination of the contract for default.

22.3 If at any time during the currency of the contract, the supplier encounters conditions hindering timely delivery of the goods and performance of services, the supplier shall promptly inform the Purchaser/Consignee in writing about the same and its likely duration and make a request to the Purchaser/Consignee for extension of the delivery schedule accordingly. On receiving the supplier's communication, the Purchaser/Consignee shall examine the situation as soon as possible and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages for completion of supplier's contractual obligations by issuing an amendment to the contract.

22.4 When the period of delivery is extended due to unexcused delay by the supplier, the amendment letter extending the delivery period shall, interalia contain the following conditions:

a. The Purchaser/Consignee shall recover from the supplier, under the provisions of the clause 23 of the General Conditions of Contract, liquidated damages on the goods and services, which the Supplier has failed to deliver within the delivery period stipulated in the contract.
b. That no increase in price on account of any ground, whatsoever, including any stipulation in the contract for increase in price on any other ground and, also including statutory increase in or fresh

imposition of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or on account of any other tax or duty which may be levied in respect of the goods and services specified in the contract, which takes place after the date of delivery stipulated in the contract shall be admissible on such of the said goods and services as are delivered and performed after the date of the delivery stipulated in the contract.

c. But nevertheless, the Purchaser/Consignee shall be entitled to the benefit of any decrease in price on account of reduction in or remission of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or any other duty or tax or levy or on account of any other grounds, which takes place after the expiry of the date of delivery stipulated in the contract.

22.5 The supplier shall not dispatch the goods after expiry of the delivery period. The supplier is required to apply to the Purchaser/Consignee for extension of delivery period and obtain the same before despatch. In case the supplier dispatches the goods without obtaining an extension, it would be doing so at its own risk and no claim for payment for such supply and / or any other expense related to such supply shall lie against the purchaser.

23. Liquidated damages

23.1 Subject to GCC clause 26, if the supplier fails to deliver any or all of the goods or fails to perform the services within the time frame(s) incorporated in the contract, the Purchaser/Consignee shall, without prejudice to other rights and remedies available to the Purchaser/Consignee under the contract, deduct from the contract price, as liquidated damages, a sum equivalent to **0.5% (Zero point Five percent) per week of delay or part thereof on delayed supply of goods and/or services until actual delivery or performance subject to a maximum of 5% (Five percent) of the contract value**. Once the maximum is reached Purchaser/Consignee may consider termination of the contract as per GCC 24.

During the above-mentioned delayed period of supply and / or performance, the conditions incorporated under GCC sub-clause 22.4 above shall also apply.

24. Termination for default

24.1 The Purchaser/Consignee , without prejudice to any other contractual rights and remedies available to it (the Purchaser/Consignee), may, by written notice of default sent to the supplier, terminate the contract in whole or in part, if the supplier fails to deliver any or all of the goods or fails to perform any other contractual obligation(s) within the time period specified in the contract, or within any extension thereof granted by the Purchaser/Consignee pursuant to GCC sub-clauses 22.3 and 22.4.

24.2 In the event of the Purchaser/Consignee terminates the contract in whole or in part, pursuant to GCC sub-clause 24.1 above, the Purchaser/Consignee may procure goods and/or services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the supplier shall be liable to the Purchaser/Consignee for the extra expenditure, if any, incurred by the Purchaser/Consignee for arranging such procurement.

24.3 Unless otherwise instructed by the Purchaser/Consignee, the supplier shall continue to perform the contract to the extent not terminated.

25. Termination for insolvency

25.1 If the supplier becomes bankrupt or otherwise insolvent, the purchaser reserves the right to terminate the contract at any time, by serving written notice to the supplier without any compensation, whatsoever, to the supplier, subject to further condition that such termination will not prejudice or affect the rights and remedies which have accrued and / or will accrue thereafter to the Purchaser/Consignee.

26. Force Majeure

26.1 Notwithstanding the provisions contained in GCC clauses 22, 23 and 24, the supplier shall not be liable for imposition of any such sanction so long the delay and/or failure of the supplier in fulfilling its obligations under the contract is the result of an event of Force Majeure.

26.2 For purposes of this clause, Force Majeure means an event beyond the control of the supplier and not involving the supplier's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the Purchaser/Consignee either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees , lockouts excluding by its management, and freight embargoes.

26.3 If a Force Majeure situation arises, the supplier shall promptly notify the Purchaser/Consignee in writing of such conditions and the cause thereof within twenty one days of occurrence of such event. Unless otherwise directed by the Purchaser/Consignee in writing, the supplier shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26.4 If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side.

26.5 In case due to a Force Majeure event the Purchaser/Consignee is unable to fulfil its contractual commitment and responsibility, the Purchaser/Consignee will notify the supplier accordingly and subsequent actions taken on similar lines described in above sub-paragraphs.

27. Termination for convenience

27.1 The Purchaser/Consignee reserves the right to terminate the contract, in whole or in part for its (Purchaser's/Consignee's) convenience, by serving written notice on the supplier at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the Purchaser/Consignee. The notice shall also indicate interalia, the extent to which the supplier's performance under the contract is terminated, and the date with effect from which such termination will become effective.

27.2 The goods and services that are complete and ready in terms of the contract for delivery and performance within thirty days after the supplier's receipt of the notice of termination shall be accepted by the Purchaser/Consignee following the contract terms, conditions and prices. For the remaining goods and services, the Purchaser/Consignee may decide:

a) To get any portion of the balance completed and delivered at the contract terms, conditions and prices; and / or

b) To cancel the remaining portion of the goods and services and compensate the supplier by paying an agreed amount for the cost incurred by the supplier towards the remaining portion of the goods and services.

28. Governing language

28.1 The contract shall be written in English language following the provision as contained in GIT clause 3. All correspondence and other documents pertaining to the contract, which the parties exchange, shall also be written accordingly in that language.

29. Notices

29.1 Notice, if any, relating to the contract given by one party to the other, shall be sent in writing or by cable or telex or facsimile and confirmed in writing. The procedure will also provide the sender of the notice, the proof of receipt of the notice by the receiver. The addresses of the parties for exchanging such notices will be the addresses as incorporated in the contract.

29.2 The effective date of a notice shall be either the date when delivered to the recipient or the effective date specifically mentioned in the notice, whichever is later.

30. Resolution of disputes

30.1 If any dispute, difference, question or disagreement arises between the parties hereto or their respective representatives at any time in connection with construction, meaning, operation, effect, interpretation or out of the contract or breach thereof, the parties shall seek to resolve such a dispute or difference by mutual consultation within a period of 30 days from the date on which the party raising the dispute, first communicated the same in writing to the other party. The existing directions, classifications, measurements, drawings and certificates of the Employer shall be final and binding upon the contractor during the progress of the works and shall not be set aside on account of non-observance of any formality, any omission, delay or error in proceeding in or about the same or on any other ground or for any reason.

30.2 In case the dispute is not settled by mutual consultation, then either party may refer the same to Arbitration by an Arbitral Tribunal consisting of three arbitrators. Each party shall appoint an arbitrator and the arbitrators so appointed shall appoint a third arbitrator who will act as presiding arbitrator.

30.3 The reference to arbitrator shall specify the matters which are in question, dispute or difference and only such dispute or differences of which the demand has been made be referred to arbitration. Notwithstanding the reference to arbitration, the contractor shall continue to duly perform his obligations under the contract.

30.4 The Award of the Arbitral Tribunal shall be final, conclusive and binding on the parties. The Arbitration shall be conducted in accordance with the provisions of Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be at Chennai. The fees of the arbitrators shall be borne by the parties nominating them and the fee of the Presiding Arbitrator, costs and other expenses incidental to the arbitration proceedings shall be borne equally by the parties.

30.5 Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

31. Applicable Law

31.1 The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

31.2 Jurisdiction

The courts at Chennai, Tamil Nadu shall have exclusive jurisdiction for all disputes and difference arising out of this contract.

32. General/ Miscellaneous Clauses

32.1 Nothing contained in this Contract shall be constructed as establishing or creating between the parties, i.e. the Supplier/its Indian Agent/Service Provider on the one side and the Purchaser on the other side, a relationship of master and servant or principal and agent.

32.2 Any failure on the part of any Party to exercise right or power under this Contract shall not operate as waiver thereof.

32.3 The Supplier shall notify the Purchaser/Consignee /the Government of India of any material change would impact on performance of its obligations under this Contract.

32.4 Each member/constituent of the Supplier/its Indian Agent/Service Provider shall be **jointly and severally liable** to and responsible for all obligations towards the Purchaser/Consignee/Government for performance of contract/services including that of its Associates/Sub Contractors under the Contract.

32.5 Indemnities

32.5.1 The Supplier/its Indian Agent/Service Provider shall at all times, indemnify and keep indemnified the Purchaser/Government of India against all claims, damages, cost and expenses arising from the incorporation in or use of work of any such articles, processes or supplies made under this agreement. Supplier shall at all times indemnify the purchaser against all claims which may be made for any infringement of any Intellectual Property Rights (IPR) while providing its services under contract for AMC or the Contract. However the liability of the Suppliers/its Indian Agents/Service Providers rose on the above circumstances is limited to the overall contract value.

32.5.2 The Supplier/its Agent/Service Provider shall, at all times, indemnify and keep indemnified the Purchaser/Consignee/Government of India against any claims in respect of any damages or compensation payable in consequences of any accident or injury sustained or suffered by its employees or agents or by any other third party resulting from or by any action, omission or operation conducted by or on behalf of the supplier/its associate/affiliate etc.

32.6 All claims regarding indemnity shall survive the termination or expiry of the contract.

SECTION – V

SPECIAL CONDITIONS OF CONTRACT (SCC)

The Special Conditions of Contract (SCC) will apply for this purchase. The corresponding clauses of General Conditions of Contract (GCC) relating to the SCC stipulations have also been incorporated below.

These Special Conditions will modify/substitute/supplement the corresponding (GCC) clauses.

Whenever there is any conflict between the provision in the GCC and that in the SCC, the provision contained in the SCC shall prevail.

1. GENERAL

These special conditions shall be read in conjunction with the General Conditions of contract, Job Specifications, Drawings and other documents forming part of this contract wherever the context so requires.

Notwithstanding the sub-division of the documents into these sections and volume every part of each shall be deemed to be supplementary to and complementary of every other part and shall be read with and into the context in so far as it may be practicable to do so.

The several documents forming the contract are to be taken as mutually explanatory of one another. In case of discrepancy the following order of precedence shall be observed:

The works described in latest approved documents like drawings, design qualification and notes thereon.

- The items in the schedule of quantities.
- Particular specifications (given in Tender documents)
- Special conditions of contract.
- General conditions of contract.
- Special Instructions to tenderers
- General Instructions to tenderers

The intending supplier shall be deemed to have visited the site and familiarized himself thoroughly with the site conditions before submitting the tender or before signing the contract. Non-familiarity with the site conditions will not be considered a reason either for extra claims or for not carrying out the work in strict conformity with the drawings and specifications.

The prices quoted should include supply, installation, testing & commissioning at site & should include all applicable taxes & duties.

2. COMPLETION TIME & LIQUIDATED DAMAGES

Over all completion time shall be as mentioned in the Schedule of Fiscal Aspect. The Liquidated Damages (LD) shall be levied at the rate of **0.5% per week maximum being 5% of Total Contract Value**, if the work is delayed beyond the stipulated completion time.

3. FAILURE TO ARRANGE COMMITTED MANPOWER /MACHINERY

The Supplier shall submit manpower and machinery / equipment proposed to be deployed to carry out the work within the stipulated time. Such committed manpower/machinery shall be considered as minimum requirement and failure to maintain the same at site shall be treated as deemed unfit. In such cases, the purchaser reserves the right to terminate the contract as per GCC clause 24.

4. ACCESS TO SITE

All necessary access to working area will have to be made and maintained by the Supplier. Such temporary constructions shall have to be removed after completion of the work or if so advised by Purchaser at any point of time at no extra cost.

5. PROPERTY RIGHTS

All materials / goods / items at site whether free issue or otherwise, other than the Supplier's construction machinery, will be property of Purchaser, which shall not be removed from site of work and shall be open to inspection by Purchaser. The Supplier shall be responsible for any theft, loss and damage to such material, items, goods etc.

6. LABOUR AT SITE

Purchaser will not allow any temporary or permanent hutments or colonies at the Work Site. The Supplier will have to make his own arrangement for such labour camp(s) away from site at his own cost.

7. WATER AND ELECTRICITY FOR CONSTRUCTIONS

The electricity, if available at site will be provided to the Supplier at a single point on a chargeable basis. The Supplier shall pay the Purchaser at the prices stated. The quantities consumed shall be determined by the Purchaser, who shall include the amounts due as deductions in Interim and final payment certificates. The Supplier shall, at his risk and cost, provide any apparatus necessary for such determination and for his use of these services. The Supplier should make his own arrangements for the providing back up power supply (like D.G sets of required capacity) during the work.

However, water required for any purpose has to be arranged by Vendor at his own cost.

8. OTHER CONTRACTS / CONCURRENT WORKS

Purchaser reserves the right to let other Suppliers work in the same area in connection with his work under similar Agreement. The Supplier shall afford other Supplier s' reasonable opportunity for the introduction and storage of their materials and the execution of their work and shall properly connect and co-ordinate his work with theirs. If any part of Supplier's or sub- Supplier's work depends for proper execution or results upon the work if any other Supplier or Sub- Supplier, the Supplier shall inspect and promptly report to Purchaser any defects in such work that render it unsuitable for such proper execution and results. Failure of the Supplier to so inspect and report shall constitute an acceptance of the other Supplier's work as fit and proper for the reception of his work.

During the progress of this contract, other construction works will also be concurrently in operation. The Supplier shall co-operate with the other Supplier s working at site to the fullest extent and shall allow reaching other every facility and co-operation for execution of this work, simultaneously and satisfactorily during the erection of machinery or execution of any other activity. Supplier may have to suspend his work partially or totally in the interest of the whole project. He may also be required to dismantle or to shift his construction plant and equipment for erection of machinery and /or any other operation. In such cases, he shall not be given any compensation on account of reduction or stoppage of labour force or dismantling, shifting of his construction plant and equipment, etc.

9. SAFETY PRECAUTIONS AT WORK

The Supplier shall make all necessary arrangements for safety of personnel working at site and ensure that all safety precautions in line with established industry practices are taken and Guide Lines issued by Statutory Authorities are complied with.

10. PROTECTION AND CLEANING

The Supplier shall protect and preserve the work from all damage or accident providing any temporary roof, window and door coverings, boxing or other construction as required by the Purchaser. This protection shall be provided for all property adjacent to the site as well as on the site.

The Supplier shall properly clean the work as it progresses and shall remove all rubbish and debris from the site from time to time as is necessary and as directed. On completion, the Supplier shall ensure that the premises and / or site are cleaned, surplus materials debris, sheds etc. removed, areas under floors cleared of rubbish, gutters and drains cleared, doors and sashes eased, locks and fastenings oiled, keys clearly labelled and handed over to the In Charge of Works so that the whole is left fit for immediate occupation or use and to the satisfaction of the Purchaser.

11. PROTECTION OF WILD LIFE

The Supplier shall ensure the safety of wild life animals in and around the site and ensure that all Statutory Regulations are complied with. He shall indemnify Purchaser against violation of Wild Life Protection Act or any such Government Regulations.

12. VALIDITY OF OFFER/RATES / PRICES

The Offer remains valid for a period of **120 days** from the date of opening of tender.

After placement of Order all the rates/prices quoted by Supplier shall remain valid till the Final Acceptance Certificate / Measurement Certificate is issued by Purchaser.

The unit rates / prices quoted by the Supplier in the offer shall be firm irrespective of variation in any quantity of individual items and/or in the total contract price.

Prices and unit rates shall be valid even if the contract is split.

Prices and unit rates of any or each item shall be valid irrespective of whether the item to be executed is located at any height/depth, any floor, inside or outside the building unless otherwise specifically mentioned.

Necessary deductions towards the Employee's State Insurance as per the Act, will be made in the Supplier's bills if necessary. The Supplier shall provide the proof of ESI payments and its adherence. The Supplier should maintain all records of labour payments (including sub Suppliers) and product as and when required by the Purchaser or ESI Authorities for assessment and recovery. In case any additional amount is demanded from the Purchaser by the authorities on any account, the Purchaser shall have the right to recover the same from the Supplier.

13. CONFIDENTIALITY

The Supplier shall not reveal the scope of supply/rates/quantities/facilities appearing in the order to anybody without the knowledge of Purchaser. Violation of this Clause will be treated as breach of Contract, in which case Purchaser will reserve the right to take necessary punitive action against the Supplier.

14. TESTING OF MATERIAL

Purchaser reserves the right to ask for any kind of test to be carried out on any construction material / consumables / finished structures / operation / performance or goods or items / bought outs. The Supplier shall bear all necessary charges for all such tests. Such tests shall be carried out by a laboratory / person approved by Purchaser.

15. ESCALATION

The rates of Supplier shall remain fixed till the completion and NO price variation on account of any increase in taxes, duties or any other reason, whatsoever, shall be payable. It is clarified that No escalation clause is applicable for this contract.

16. SUPPLIER'S INABILITY TO SUPPLY MATERIAL/ PROVIDING THE SERVICE

In case of Supplier fails to supply any item of material / services covered under contract then Purchaser will be at liberty to procure the same from open market / engaging other parties to perform the required services at the risk & cost of the Supplier and recover the same from forthcoming running bill or Security Deposit/Bank Guarantee.

17. PUNITIVE MEASURES

Purchaser will decide on punitive measures wherever reference to punitive measures or otherwise due to breach of contract is indicated in the clauses above. Decision of Purchaser in such matters shall be binding on the Supplier.

18. AMBIGUITIES IN TERMS & CONDITIONS/ QUANTITIES.

In case of any dispute or ambiguity in the interpretation of any condition contained both in the Agreement and the Special Conditions of Contract the interpretation of the Special Conditions of Contract shall prevail.

In case of interpretation of any item description in the schedule of quantities and the equivalent specifications, the item description given in the schedule of quantities shall prevail.

19. CHANGES IN CONSTITUTION

Before any change is made in the constitution of the firm, the prior approval is to be obtained by the Supplier in writing of the Accepting Authority. If the Supplier is an individual or a proprietary concern and the individual or the proprietor dies and if the Supplier is a partnership concern and one of the partners dies, then the Accepting Authority reserves the right to cancel the contract, if the Accepting Authority is not satisfied that the legal representatives of the individual firm or the proprietor of the proprietary concern and in the case of partnership, the surviving partners are capable of carrying out and completing the contract.

20. UNDER PAYMENT / OVER PAYMENT

The Purchaser reserves the right to carry out past payments, audit and technical examinations of the trial bill including all supporting vouchers, abstracts, etc., If as a result of such audit and technical examination any overpayment is discovered, it shall be recovered from any other sum due to the Supplier, which may be available with the Purchaser or he shall pay the claim on demand.

Any amount due to the Supplier under this Contract for underpayment may be adjusted against any amount then due or which may at any time thereafter become due before payment is made to the Supplier.

In case of any conflict between the description of items in schedule of quantities, specifications, drawings and other tender documents, the decision of the Purchaser, in writing, shall be final binding and conclusive for the purpose of this contract. The Supplier in any case shall not delay or stop the work for the questions or disputes being referred to arbitration but shall proceed with work with all diligence until the decision of the arbitrator and shall abide by arbitrators decision.

i. The Supplier shall be responsible, in all respects, for the co-ordination of all the services work including electrical, piping and modular works or works of other Purchaser appointed agencies. Supplier shall ensure proper co-ordination for the inter-dependent / related activities between himself, services sub-Suppliers and other nominated, Specialist Suppliers etc.

ii. The Supplier shall arrange the water, electricity and scaffoldings required on their own.

iii. The Supplier shall be responsible to work out a co-ordinated work schedule with the HVAC, Civil, Electrical, Mechanical &Piping and other nominated Suppliers.

iv. No other claim shall be entertained from the Supplier on the plea that the work has been executed in the above circumstances or under difficult conditions. It shall be the responsibility of the Supplier to enforce necessary discipline among his workers and staff to ensure smooth working at the site in a spirit of co-operation and amity with all other agencies. In case of any dispute, decision of Purchaser or Purchaser shall be final and binding to the Supplier.

v. The Supplier is made explicitly clear that the work is to be carried out in co-ordination with all other nominated Suppliers/ agencies, which shall be engaged to execute other services of the project. The Supplier shall submit to the Purchaser's approval, immediately the following information in order to proceed with the work.

vi. Exact Layout and details of the temporary work that the Supplier wants to carry out to fulfil his obligations under the contract.

vii. A general layout of storage space for material for the execution of work within stipulated time period.

viii. Depending on the exigencies at the site the temporary offices, stores etc. may have to be moved or shifted and the Supplier shall do so, if so required by the Purchaser / Consultant at no extra cost to the Purchaser.

ix. Purchaser shall have full power to get any materials of work to be tested by an independent agency at Supplier's expense in order to prove the soundness and adequacy.

x. If any material / equipment are supplied by the Purchaser to the Supplier free of cost, the Supplier shall receive the same at site, handle with care and store them as directed by the Purchaser. The Supplier shall be responsible for the safe custody and shall insure all materials against theft and damage by fire. The Supplier shall maintain records of consumption on daily basis.

xi. The Supplier shall ensure cleanliness and keep the site free from all debris, hazardous material, loose wires, open fires or any other materials and avoid damage due to accidents, negligence etc. All the above measures including fencing etc. required to be provided during the time period of the contract, shall be provided by the Supplier at no expense to the Purchaser. The provision of all these measures does not absolve the Supplier of his liabilities as per the contract.

xii. It shall be the responsibility of the Supplier to ensure that his workmen do not trespass into areas and buildings adjacent to the construction site. The Supplier shall enforce proper discipline in this regard by making proper arrangements.

xiii. To facilitate satisfactory completion of the work under this contract, and to co-ordinate work with other agencies working at the site, meetings will be held at the time and venue decided by the Consultant / Purchaser. During these meetings progress of various works will be reviewed and those matters needing clarifications / decisions to expedite the work will be taken up.

xiv. During progress of the work, completed portion of the building may be occupied and put to use by the Purchaser. The Supplier shall however remain fully responsible for the maintenance of all the work till the entire work covered by the Supplier is satisfactory completed and handed over to the Purchaser.

xv. Safe custody of all materials and products supplied by the Supplier shall be his own responsibility till the final taking over by the Purchaser. He should therefore employ sufficient staff for watch and ward at his own expenses.

xvi. It shall be the responsibility of the Supplier to study carefully all the drawings, instructions etc. and point out discrepancies and obtain clarifications, if any, in writing before taking up the work. He shall also be responsible to ensure that the work is carried out in accordance with Local Bye-Laws in all respects, and to ensure that he obtains all prior sanctions from all the Competent Local Authorities before he takes up the work. If, as a result of his failure to do so, in spite of the works having been carried out as per the drawings and instruction issued by the Consultant and /or the Purchaser, and/or in the presence of the representative(s) of the Consultant / Purchaser, the Supplier himself shall be solely responsible and if so directed, dismantle and reconstruct at his own cost the work/item(s) of work as per such directions. No claims in this regard will be entertained.

xvii. It shall be the sole responsibility of the Supplier to ensure all safety measures giving proper prior notices etc. and obtaining prior permission from concerned local authorities as per Bye-Laws or directions issued by them, all at his own cost. No claim of the Supplier in this regard shall be entertained.

xviii. With the submission of the tender, the Suppliers declares and agrees that all the labour and requisite materials required for the work are available for completion of the work within the period stipulated for completion of the work.

xix. Any material / item / fitting / fixtures rejected by the Purchaser / Consultant shall be removed from the site within 48 hours of issue of instructions to this effect by the Purchaser / consultant. Failing this, the Purchaser shall have the rights to get these so removed at the Supplier's cost and the Supplier shall have no claim whatever in this regard.

xx. The Supplier is alone responsible, for any discrepancy arising out of the definition / interpretation etc. of any matter connected with the execution of the work, which has not been got clarified prior to submission of tenders as required and all consequences arising there from.

xxi. The Supplier shall also include in his quoted rate barricading / fencing of construction activity area. All materials, fabrication yards, stores, manpower are to be contained within the barricaded area. The Supplier shall not be allowed to extend his activities beyond this area.

xxii. Electricity, if available at site will be provided to the Supplier at a single point on a chargeable basis. The Supplier should make his own arrangements for the providing back up power supply (like D.G sets of required capacity) during the work.

xxiii. Water has to be arranged by the Supplier at his own cost.

xxiv. The Supplier will be provided with open space free of cost for constructing temporary site office near the construction area.

xxv. It is essential that the works site be kept in an orderly and neat manner at all times. Stacking of materials, arrangement of fabrication yards, water tank for construction, equipment etc. shall be free from

obstructions and easy to survey and inspect. The Purchaser should have the right to get such work as is necessary to ensure proper maintenance of the works site at the Suppliers cost, in case the Supplier fails to comply with the requirements.

xxvi. The Supplier has to meet all safety requirements as laid down by Purchaser at their own cost.

xxvii. The Supplier shall use only steel scaffolding and not bamboos for any kind of work.

21. TAXES AND DUTIES

Any variation in statutory levies/taxes within the contractual delivery period shall be to HBL's account subject to production of documentary evidence and Govt. notifications by the Supplier & beyond contractual delivery period, upward variation shall be to Supplier's account. Unit Prices quoted by the bidder shall be firm and valid, irrespective of any statutory variations in Taxes/levies.
In case any taxes, duties are not clearly specified in Financial Bid then it will be presumed that no such tax/levy is applicable or payable. Blank field in Financial Bid shall be treated as 'Inclusive' in the quoted price.

A) The total composite price shall comprise of unit price and all other components of price need to be individually indicated quoted against the goods/material/service, it proposes to provide under the contract in the following manner:

I. The Basic unit price (Ex-Factory Price) of the goods/services/materials, Excise Duty, Sales Tax, Freight, Forwarding, Packing, service tax, insurance and any other levies/charges already paid or payable by the contractor/supplier shall be quoted separately.

II. The liability to pay all taxes, levies etc., shall be of contractor and HBL will not entertain any claim whatsoever in this respect.

B) No concessional form except Sales Tax form 'C' for the items as specified in the schedule of works and meant for use in HBL, shall be provided by HBL. Form 'C' shall be provided by HBL only on the specific request of the contractor.

· For the purpose of evaluation of financial Bid, composite price inclusive of all taxes and levies will be considered.

· The unit wise cost/break up is necessary for the purpose of information and verification of composite price so quoted by the contractor/supplier.

· The contractor/supplier shall submit to HBL documents/proof of payment of all taxes/levies along with exemption certificate if any, to avail applicable benefits by HBL.

22. STATUTORY VARIATIONS:

A. However pursuant to the constitution (forty-sixth amendment) Act, 1982, if any further tax or levy is imposed by statute, after the last date of receipt of tenders, and the contracts thereupon necessarily and properly pays such taxes/levies, the contractor shall be reimbursed the amount so paid, provided such payment, if any, is not in the opinion of the Engineer-in-charge (whose decision shall be final and binding) be attributable to delay in execution of work within the control of the contractor.

B. In case of statutory variation in regard to taxes/levies, within the stipulated date of completion of individual agreement, the same shall be paid or recovered as per the actual against documentary proof. However beyond this period HBL will take advantage of any reduction in taxes/levies but will not pay extra on account of increase in taxes/levies.

23. ADVANCE BANK GUARANTEE:

When the vendor has supplied the Equipment in complete to the site and fulfilled all his supply obligations as per the contract and any delay on the part of the purchaser resulting in deferment in the services/Execution of the contract, then the purchaser may decide on returning the ABG on its expiry.

SECTION – VI

LIST OF REQUIREMENTS

Schedule No	Equipment name	Capacity	Qty. (Nos)
I	Vortex Mixer		2
II	Table top cooling centrifuge	1.8 ml to 50 ml	1
III	Bag sealing machine		2
IV	Deep freezer (Ultra low)	250 Lts	11
		400 Lts	1
V	Hot air oven	200 Lts	1
		500 Lts	3
VI	Peristaltic pump	Flow rate: 100-3000 ml/min.	13
		Flow rate: 1000-10000 ml/min.	5
		Flow rate: 0-3 l/min.	10
VII	Air Sampler		11
VIII	Apo trinocular stereomicrosc ope		1
IX	Chiller water bath	20L	1
X	Conductivity meter	Should be operated at 80^0C	7
XI	Cooling centrifuge	6 lts (1.5*4)	1
XII	Cooling batch centrifuge	Floor mounted, 6lts, rpm 10000 max.	3
XIII	Deep freezer (Low)	250 lts	2
XIV	Deep freezer (Low- Horizontal)	460 lts	3
XV	Egg Incubator	1000 eggs	1

Schedule No	Equipment name	Capacity	Qty. (Nos)
XVI	GMP Refrigerator	300 L	8
XVII	Gas Chromatograp hy		2
XVIII	HPLC system		1
XIX	Incubator	200 Lts	3
		800-1000 L	6
XX	Inspissator		1
XXI	Inverted fluorescence microscope		1
	Upright Microscope		2
	Inverted microscope		4
XXII	LN2 storage container	-70^{0}C, 180 L, Vertical	4
XXIII	Magnetic stirrer with hot plate	To hold 20L glass bottle capacity	1
XXIV	Magnetic Stirrer	To hold 20 L bottle	4
		To hold 5L, 15 L bottle	2
		platform 400mm 50 L carboy with RPM 0-1200	11
XXV	Micro Aerophilic condition incubator		2
XXVI	PCR		1
XXVII	pH & Conductivity meter		5
XXVIII	pH meter		8
XXIX	Refrigerated Shaker Incubator (vertical)	2Litrs *6 flask	1
XXX	Roller culture Apparatus		4
XXXI	Shaker Incubator	200Lts	1
XXXII	Spectrophotometer UV with CPU	200-1100nm	2

Schedule No	Equipment name	Capacity	Qty. (Nos)
XXXIII	Table top centrifuge	1 ml tubes	1
XXXIV	Thermohygrometer		28
XXXV	Ultra sonication bath	12.2 L	1
XXXVI	Vacuum Pump		1
XXXVII	Potentiometer		1
XXXVIII	Water bath	20 to 100 ˚C	2
		30 L	2
XXXIX	Weighing Balance	220g	2
		810g	1
		410g	1
		220g	1
		150Kg	1
		15Kg	1
		1 g to 600g Readability - 1mg	3
		10g to 10Kg (Readability - 100mg)	1
		0.1 to 1000 g	1
		0.1to 40 kg	5
		3-20 kg	1
		Upto 3 Kg	1
		0.1to 40 kg	1

Part II: Required Delivery Schedule:

As mentioned in the schedule of Fiscal Aspects

Part III: Scope of Incidental Services:

Installation & Commissioning, Supervision, Demonstration, Trial run and Training etc. as specified in GCC Clause 13

Part IV: Turnkey (if any) as per details in General Technical Specification.

Part V: AMC as per details in Technical Specification.

Part VI: Required Terms of Delivery and Destination.

a) For Indigenous goods or for imported goods if supplied from India:
At Consignee Site
Insurance shall be borne by the Vendor.

b) For Imported goods directly from abroad:
The foreign tenderers are required to quote their rates on DAP at Consignee site basis giving breakup of the price as per the Proforma prescribed in the Price Schedule.
The shipping arrangements shall be made in accordance with the instruction of Ministry of Shipping & Transport, New Delhi, India as detailed in Section XXII.
Insurance shall be borne by the Vendor.

Destination/Consignee details are given in Section XX

Section – VII

Technical Specifications

Note 1: Tenderer's attention is drawn to GIT clause 17 and GIT sub-clause 10.1 under heading (c) preparation of tenders. The tenderer is to provide the required details, information, confirmations, etc. accordingly failing that it's tender is liable to be ignored.

Note 2: General: Bidders are requested to make sure that they should attach the list of equipments for carrying out routine and preventive maintenance wherever asked for and should make sure that Electrical Safety Analyser / Tester for Process equipments to periodically check the electrical safety aspects as per BIS Safety Standards IS-13540 which is also equivalent to IEC electrical safety standard IEC-60601 is a part of the equipments. If the Electrical Safety Analyzer/Tester is not available they should provide a commitment to get the equipments checked for electrical safety compliance with Electronic Regional Test Labs / Electronics Test and Development Centres across the country on every preventive maintenance call.

Note 3: OPTIONAL ITEMS: Bidders are requested to quote for all the available options as asked in the bidding document with reasonable pricing. However the pricing for optional items will not be considered for price comparison for ranking purpose. If the firm has not quoted for any optional item (except the items of turnkey- if any) their offer will be treated as TECHNICALLY RESPONSIVE if otherwise meeting the specification.

Refer the following Annexures for the details on Datasheets

Annexures: Datasheets of all Schedules

DataSheets DS1 & DS2

Note: Specifications packages in separate folder.

Note:

1. **The available clear height inside any of the rooms is 3 m. Vendors to check suitability of installing their equipment's in this available area and height and revert back with their views.**

   If no views are received from any vendors before or during the pre-bid meeting, it is assumed that the vendor is confident of installing their equipment's with-in the area and height available. No further claims shall be entertained.

2. **The extent of automation and optional additional features may vary during the pre-bid discussion.**

3. **The quantity of equipment mentioned in the list may vary during ordering.**

GENERAL TECHNICAL SPECIFICATIONS

GENERAL POINTS:

1. Warranty:

a) One year Comprehensive Warranty as per Conditions of Contract of the TE document for complete equipment and Turnkey (if any) Work from the date of satisfactory installation, commissioning, trial run & handing over of equipment to CONSIGNEE.
b) 98% up time Warranty of complete equipment with extension of Warranty period by double the downtime period on 24 (hrs) X 7 (days) X 365 (days) basis.
c) All software updates should be provided free of cost during Warranty period.

2. After Sales Service:

After sales service centre should be available at the city of CONSIGNEE on 24 (hrs) X 7 (days) X 365 (days) basis. Complaints should be attended properly, maximum within 48 hrs. The service should be provided by Tenderer/Indian Agent. Undertaking by the Principals that the spares for the equipment shall be available for at least 10 years from the date of supply. However if the manufacturer/agent does not have the service centres in India will have to set up the same within 45 days after award of the contract.

3. Training:

On Site training to operators/ Technicians/ staff is to be provided by Principal/ Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the consignee.

4. AMC of subject equipment with Turnkey (if any):
   a) The cost of AMC which includes calibration of the Equipment along with Calibration Certificate, the necessary calibration tools, labour charges as per technical/ service /operational manual of the manufacturer, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any).
   b) The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. **The taxes to be paid extra, to be specifically stated**. In the absence of any such stipulation, the price will be taken inclusive of such taxes and no claim for the same will be entertained later.
   c) Cost of AMC will be added **for Ranking/Evaluation purpose**.
   d) The payment for AMCn will be made on Half Yearly basis, after submission of the AMC Certificate, duly certified by end user.
   e) Failure of the point 4.a by the supplier, may lead to the forfeiture of the Bank Guarantee for AMC.
   f) The payment of AMC will be made as stipulated in GCC Clause 21.

Turnkey (if any):

(i) The Tenderer shall examine the existing site where the equipment is to be installed.

(ii) Turnkey (if any) comprises of Supply, Installation, Commissioning and validation of the Lab equipment (Phase-3).

(iii) Tenderers to quote prices indicating break-up of prices of the Machine.

(iv) The Turnkey costs (if any) may be quoted (Inclusive of all taxes /duties) in Indian Rupee will be added for Ranking Purpose.

Section – VIII

Quality Control Requirements (for each schedule)

(Proforma for equipment and quality control employed by the manufacturer(s) Tender Reference no.

Date of opening
Time
Name and address of the Tenderer:

Note: All the following details shall relate to the manufacturer(s) for the goods quoted for.

01 Name of the manufacturer
   a. Full postal address
   b. Full address of the premises
   c. Email ID
   d. Telephone number
   e. Fax number

02 Plant and machinery details

03 Manufacturing process details

04 Monthly (single shift) production capacity of goods quoted for
   a. normal
   b. maximum

05 Total annual turn-over (value in Rupees) for the last three calendar years excluding the year of tender opening:

06 Quality control arrangement details
   a. for incoming materials and bought-out components
   b. for process control
   c. for final product evaluation

07 Test certificate held
   a . type test
   b . BIS/ISO certification
   c . any other

08 Details of staff
   a. technical
   b skilled
   c unskilled

09 Please furnish documentation details with clarifications etc as asked for at the end of the equipment specification.

Signature and seal of the Tenderer

Section – IX

Qualification Criteria

1. Bidders must be a manufacturer or an authorized dealer/agent of the original equipment/s. In case of authorized dealer/agent, the Manufacturer's Authorization Certificate/Form (as shown in Section - XIV of tender document) from the manufacturer to be attached.

2. Net worth of the company shall be positive during the last three financial years. The balance sheet, profit and loss account for last three financial years certified by a Chartered Accountant shall be submitted.

3. The bidder must have supplied and installed the equipment within the schedule during the last five financial year as per the schedules. Purchase Order Copy/ Installation Certificate / Completion Certificate / Service report/Performance Certificate to be provided as per table below.

4. The average annual turnover of the tenderer during the last three financial year must be as indicated in the table below. Furnish the information under section B.

Table for Point 3 and 4:

Schedule No	Equipment name	Capacity	Qty (Nos)	Annual Turnover (in Rs.)
I	Vortex Mixer		2	64000
II	Table top cooling centrifuge	1.8 ml to 50 ml	1	600000
III	Bag sealing machine		2	240000
IV	Deep freezer (Ultra low)	250 Lts	11	1925000
		400 Lts	1	200000
V	Hot air oven	200 Lts	1	175000
		500 Lts	3	585000
VI	Peristaltic pump	Flow rate: 100-3000 ml/min.	13	1430000
		Flow rate: 1000-10000 ml/min.	5	950000
		Flow rate: 0-3 l/min.	10	1100000
VII	Air Sampler		11	2200000
VIII	Apo trinocular stereomicrosc ope		1	600000
IX	Chiller water bath	20L	1	100000

Schedule No	Equipment name	Capacity	Qty (Nos)	Annual Turnover (in Rs.)
X	Conductivity meter	Should be operated at 80^{0}C	7	630000
XI	Cooling centrifuge	6 lts (1.5*4)	1	1200000
XII	Cooling batch centrifuge	Floor mounted, 6lts, rpm 10000 max.	3	4500000
XIII	Deep freezer (Low)	250 lts	2	300000
XIV	Deep freezer (Low- Horizontal)	460 lts	3	525000
XV	Egg Incubator	1000 eggs	1	750000
XVI	GMP Refrigerator	300 L	8	1780000
XVII	Gas Chromatograp hy		2	3500000
XVIII	HPLC system		1	1400000
XIX	Incubator	200 Lts	3	1800000
		800-1000 L	6	3600000
XX	Inspissator		1	350000
XXI	Inverted fluorescence microscope		1	800000
	Upright Microscope		2	300000
	Inverted microscope		4	600000
XXII	LN2 storage container	-70^{0}C, 180 L, Vertical	4	1284000
XXIII	Magnetic stirrer with hot plate	To hold 20L glass bottle capacity	1	50000
XXIV	Magnetic Stirrer	To hold 20 L bottle	4	600000
		To hold 5L, 15 L bottle	2	300000
		platform 400mm 50 L carboy with RPM 0-1200	11	1650000

Schedule No	Equipment name	Capacity	Qty (Nos)	Annual Turnover (in Rs.)
XXV	Micro Aerophilic condition incubator		2	1200000
XXVI	PCR		1	450000
XXVII	pH & Conductivity meter		5	375000
XXVIII	pH meter		8	480000
XXIX	Refrigerated Shaker Incubator (vertical)	2Litrs *6 flask	1	400000
XXX	Roller culture Apparatus		4	5446000
XXXI	Shaker Incubator	200Lts	1	320000
XXXII	Spectrophoto meter UV with CPU	200-1100nm	2	450000
XXXIII	Table top centrifuge	1 ml tubes	1	900000
XXXIV	Thermohygro meter		28	42000
XXXV	Ultra sonication bath	12.2 L	1	107500
XXXVI	Vacuum Pump		1	50000
XXXVII	Potentiometer		1	125000
XXXVIII	Water bath	20 to 100 ˚C	2	250000
		30 L	2	250000
XXXIX	Weighing Balance	220g	2	400000
		810g	1	200000
		410g	1	200000
		220g	1	200000
		150Kg	1	200000
		15Kg	1	200000
		1 g to 600g Readability - 1mg	3	200000

Schedule No	Equipment name	Capacity	Qty (Nos)	Annual Turnover (in Rs.)
		10g to 10Kg (Readability - 100mg)	1	200000
		0.1 to 1000 g	1	200000
		0.1to 40 kg	5	200000
		3-20 kg	1	170000
		Upto 3 Kg	1	100000
		0.1to 40 kg	1	200000

Note:

- In support of above the Tenderer shall furnish the details in the below tables.
- The manufacturer as well as the Tenderer/ Indian Agent shall furnish Satisfactory Performance cum Installation Certificate/purchase orders/bill of entry in respect of above, duly translated in English and duly notarized in the country of origin, along with the tender.
- The Tenderer shall furnish a brief write-up, packed with adequate data explaining and establishing his available capacity/capability (both technical and financial) to perform the Contract (if awarded) within the stipulated time period, after meeting all its current/present commitments. The Tenderer shall also furnish details of Equipment and Quality Control in the enclosed Section below.
- The Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening certified by a Chartered Accountant should be submitted as part of the tender
- Notwithstanding anything stated above, the Purchaser reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily before deciding on award of Contract, should circumstances warrant such an assessment in the overall interest of the Purchaser. The Purchaser reserves the right to ask for a free demonstration of the quoted equipment to similar/identical specification at a pre-determined place acceptable to the purchaser for determining technical responsiveness, before the opening of the Financial Bid.

PROFORMA:

SECTION (A). GENERAL INFORMATION:		
1	Name of Company	
2	Registration No.	
3	Number of Years in Operation	
4	Registered Address	
5	Operating Address	
6	Telephone No	
7	Telefax	
8	Email Address	
9	SERVICE TAX No.	
10	PAN No.	
11	TIN No.	

SECTION (B). FINANCE			
1	**Name & Address of Banks and Branches used :**		
1.1			
1.2			
1.3	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
2	What is your average annual invoiced sales value (based on past previous 5 year's records) for each of the type of equipment's under consideration.		
	Equipment Name: ---------- (If more than one equipment, enclose the same separately)		
2.1	Year 1	_____ (Value in Lakhs)	
	Year 2	_____ (Value in Lakhs)	
	Year 3	_____ (Value in Lakhs)	
	Year 4	_____ (Value in Lakhs)	
	Year 5	_____ (Value in Lakhs)	
2.2	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
3	Annual Turnover of the Firm/ company:		
3.1	2015 – 2016:	_____ (Value in Lakhs)	
	2014 – 2015:	_____ (Value in Lakhs)	
	2013 – 2014:	_____ (Value in Lakhs)	
3.2	Documentary evidence (duly signed & stamped) must be enclosed.		❑ Yes ❑ no
4	Bidders are to submit copy of valid current Income Tax Return submitted, Sales Tax Registration failing which their offer may be liable to be rejected.		❑ Yes ❑ no

SECTION (C) EXPERIENCE:

1	**Past Project Experience:** 1. The bidder must have supplied and installed the equipment within the schedule during the last five financial year as per the schedules. Purchase Order Copy/ Installation Certificate / Completion Certificate / Service report/Performance Certificate to be provided as mentioned in the eligibility criteria.

Sr. No.	Year awarded	Project Name	Equipment's Supplied	CONTRACT VALUE (INR)	CLIENT NAME & REFERENCE (Contact details)	Facility Approved by: (Name of approving agency)
1.1						
1.2						
1.3						
1.4						
1.5						
1.6						
1.7						
1.8						
1.9						
1.10						
	Documentary evidence of work completion certificate duly signed & stamped must be enclosed including the evidence of the facility having approved by regulatory agencies.					❑ Yes ❑ no
2	**Details of Ongoing project:**					

S. No.	Year awarded	Project Name	Equipment's Supplied	CONTRACT VALUE (INR)	CLIENT NAME & REFERENCE (Contact details)	Remarks
2.1						
2.2						
2.3						
2.4						
2.5						
	Documentary evidence of the same to be enclosed					❑ Yes ❑ no

SECTION (D). QUALITY		
1	**ISO CERTIFICATION**	
	Is your company ISO certified, if so mention the certification number and enclose the photocopy of the certificate: ISO_____ ISO_____ ISO_____	❑ Yes ❑ no
2	Enclose the company Quality policy	❑ Yes ❑ no
3	The equipment supplied should comply with the following guidelines / standards. Note: Subject to the kind of equipment supplied.	❑ Yes ❑ no
3.1	**cGMP-Regulations**	❑ Yes ❑ no
3.1.1	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15	❑ Yes ❑ no
3.1.2	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs: General.	❑ Yes ❑ no
3.1.3	21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals.	❑ Yes ❑ no
3.1.4	Schedule “M” GMP	❑ Yes ❑ no
3.1.5	21 CFR Part 11: Electronic Records; Electronic Signatures	❑ Yes ❑ no
3.2	**FDA Guidance for Industry**	❑ Yes ❑ no
3.2.1	Sterile Drug Products Produced by Aseptic Processing	❑ Yes ❑ no
3.3	**GAMP**	❑ Yes ❑ no
3.3.1	The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 5.	❑ Yes ❑ no

3.4	**CE Conformity**	
3.4.1	Deleted	❑ Yes ❑ no
3.5	**Operating safety act**	
3.5.1	The requirements of the Operating safety act must be observed.	❑ Yes ❑ no
3.6	**ISO 14664**	
3.6.1	Clean rooms and Associated Controlled Environment	❑ Yes ❑ no

Section (E). ATTACHMENTS

S. No.	Please provide the following documents in your submissions:	Enclosed
1	Company Brochure / Literature	❑ Yes ❑ no
2	Product profile	❑ Yes ❑ no
3	Technical Details of equipment's	❑ Yes ❑ no
4	Name & Address of Banks and Branches used : (duly signed & stamped)	❑ Yes ❑ no
5	**Annual turnover for the following years**	
	2015 - 2016 : Balance sheet (duly signed & stamped)	❑ Yes ❑ no
	2014 – 2015: Balance sheet (duly signed & stamped)	❑ Yes ❑ no
	2013 – 2014: Balance sheet (duly signed & stamped)	❑ Yes ❑ no
6	current Income Tax Return	❑ Yes ❑ no
	Sales Tax Registration	❑ Yes ❑ no
7	Past project experience: Completion certificate:	❑ Yes ❑ no
8	Ongoing project details.	❑ Yes ❑ no
9	ISO Certificates	❑ Yes ❑ no
10	Company policies	❑ Yes ❑ no

Section (E). ATTACHMENTS		
S. No.	**Please provide the following documents in your submissions:**	**Enclosed**
11	Equipment list / scope of supply	❑ Yes ❑ no

Signature and seal of the Tenderer

**** The documentary proof will be a certificate (enclosed) from the consignee/end user/purchaser with cross-reference of order no. and date in the certificate duly notarised certification authenticating the correctness of the information furnished. If at any time, information furnished is proved to be false or incorrect, the earnest money and or performance security furnished will be forfeited .such certificates from a third party or middleman other than actual end user/purchaser will not be accepted.**

FORMAT OF PERFORMANCE CERTIFICATE

To whom it may concern

Date. _____

Certified that M/s ---------- (name & address of the manufacturer) supplied us ----------Nos (indicate quantity) of equipment, ---------- (indicate name of the equipment) against our order no ----------dt ---------- (please indicate order no & date as figuring in the performance statement). The equipment was installed, commissioned & handed over to us on ---------- (indicate date) & since then the equipment has been working to our entire satisfaction.

Section – X

TENDER FORM

Date_____
To

_____

HLL Biotech Limited, Chennai

Ref. Your TE document no. _____dated _____
We, the undersigned have examined the above mentioned TE document, including amendment/corrigendum no. _____, dated _____ (*if any*), the receipt of which is hereby confirmed. We now offer to supply and deliver_____ *(Description of goods and services)* in conformity with your above referred document for the sum of _____ (total tender amount in figures and words), as shown in the price schedule(s), attached herewith and made part of this tender.

If our tender is accepted, we undertake to supply the goods and perform the services as mentioned above, in accordance with the delivery schedule specified in the List of Requirements.

We further confirm that, if our tender is accepted, we shall provide you with a performance security of required amount in an acceptable form in terms of GCC clause 5, read with modification, if any, in Section - V – "Special Conditions of Contract", for due performance of the contract.

We agree to keep our tender valid for acceptance as required in the GIT clause 19, read with modification, if any in Section - III – "Special Instructions to Tenderers" or for subsequently extended period, if any, agreed to by us. We also accordingly confirm to abide by this tender up to the aforesaid period and this tender may be accepted any time before the expiry of the aforesaid period. We further confirm that, until a formal contract is executed, this tender read with your written acceptance thereof within the aforesaid period shall constitute a binding contract between us.

We further understand that you are not bound to accept the lowest or any tender you may receive against your above-referred tender enquiry.

We confirm that we do not stand deregistered/banned/blacklisted by any Govt. Authorities.

We confirm that we fully agree to the terms and conditions specified in above mentioned TE document, including amendment/ corrigendum if any

---

(Signature with date)

(Name and designation) Duly authorised to sign tender for and on behalf of

SECTION – XI A PRICE SCHEDULE

PRICE SCHEDULE FOR DOMESTIC GOODS OR GOODS OF FOREIGN ORIGIN LOCATED WITHIN INDIA

1	2	3	4	5						6
				Price per unit (Rs.)						
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Ex - factory/ Ex -warehouse /Ex-showroom /Off - the shelf (a)	Packing and Forwarding charges (b)	Incidental Services (including Installation & Commissioning, Supervision, Demonstration ,Training, Documentation and Qualification) at the Consignee's site c)	GST on the base price (d)		Unit Price (at Consignee Site) basis € =a+b+c+d	Total Price (at Consignee Site) basis (Rs.) 4 x 5(e)

* The price break up for AMC charges to be given separately as per the Price Schedule-XI C.

NB: Unit price shall be written in figures and words

Total Tender price in Rupees: _____

In words:

_____

_____

Insurance shall be under Vendor's scope.

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for AMC after warranty shall be quoted separately as per Section – XI – Price Schedule C

Name_____

Business Address_____

Place: _____ **Signature of Tenderer** _____

Date: _____ **Seal of the Tenderer**_____

SECTION – XI B PRICE SCHEDULE

PRICE SCHEDULE FOR GOODS TO BE IMPORTED FROM ABROAD

Schedule. No	Equipment	Capacity / specification	Quantity	Supply	
				Currency___	Currency___
				Unit Price	Total Price
Gross FOB Price at sea / airport of Lading (A)					
Insurance & Freight (B)					
Net CIP Port of destination by Air/Sea C = (A+B)					
Customs duty % & HS Code					
Customs Clearance & Handling Charges (INR)					
Loading / Unloading / Inland Transportation & Incidental cost till Consignee's site(INR)					
Installation, Commissioning, Supervision, Demonstration, Training Documentation and Qualification at the consignee's site(INR)					
Total Price in Foreign Currency					
Total Price in INR				0	
Grand Total (Supply ,Installation, Commissioning & Validation) INR					

* The price break up for AMC charges to be given separately as per the Price Schedule-XI C.

** To be paid in Indian Currency (Rs.) or to the principal in their currency

Total DAP at Consignee site price in figures:

_____

And in words:

_____

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for AMC after warranty shall be quoted separately as per Section – XI – Price Schedule C
3. The Tenderer will be fully responsible for the safe arrival of the goods at Consignee Site.
4. The bidders break up of prices under various columns are for comparison of prises up to delivery of goods at consignee's site for tender evaluation and will be allowed on actual basis subject to bidders quoted prices as ceiling under various heads which will be adjusted later against balance payment.
5. The quoted price should be bidder's best lowest rate supported with original proforma invoice from the foreign manufacturers Indian Agent to be paid in Indian Currency.

Name_____

Business Address_____

Place: _____ **Signature of Tenderer** _____

Date: _____ **Seal of the Tenderer**_____

SECTION – XI C PRICE SCHEDULE

PRICE SCHEDULE FOR ANNUAL MAINTENANCE CONTRACT AFTER WARRANTY PERIOD

PRICE SCHEDULE FOR ANNUAL MAINTENANCE CONTRACT AFTER WARRANTY PERIOD

1	2	3	4		5
Schedule No.	BRIEF DESCRIPTION OF GOODS	QUANTITY. (Nos.)	Annual Maintenance Contract Cost for Each Unit year wise*.		Total Annual Comprehensive Maintenance Contract Cost for 2 Years [3 x (4A+4B)]
			1st	2nd	
			A	B	

*** After completion of Warranty period**

NOTE:-

1. In case of discrepancy between unit price and total prices, THE UNIT PRICE shall prevail.
2. The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual, labour, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any).
3. The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. **The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.**
4. Cost of AMC will be added for Ranking/Evaluation purpose.
5. The payment of AMC will be made as per clause GCC clause 21.1 (D).
6. The uptime warranty will be 98 % on 24 (hrs) X 7 (days) X 365 (days) basis or as stated in Technical Specification of the TE document.
7. All software updates should be provided free of cost during AMC period.
8. The stipulations in Technical Specification will supersede above provisions
9. The supplier shall keep sufficient stock of spares required during Annual Maintenance Contract period. In case the spares are required to be imported, it would be the responsibility of the supplier to import and get them custom cleared and pay all necessary duties.
10. Agency commission may be shown in separate column in price schedule.

11. The cost of spares required during the preventive maintenance/ breakdown maintenance during the AMC shall be paid extra at actual by the supplier.

Commercial aspects of AMC shall be read as

I. AMC will commence from the date of expiry of the warranty period.
II. The above mentioned value for Annual Maintenance Contract (AMC) includes preventive maintenance, breakdown maintenance, labour, after satisfactory completion of Warranty period.
III. The contractor should submit a performance bank guarantee equivalent to 10% of the amount of AMC charges for 2 years, valid for the period of AMC on entering into the agreement by the client.
IV. The payment of AMC will be made on half yearly basis, after satisfactory completion of said period, duly certified by Client. The payment will be made in Indian Rupees.
V. During AMC period, the contractor is required to visit the site at least once in 6 months commencing from the date of the successful completion of warranty period for preventive maintenance. Failure to perform this condition by the contractor, may lead to the forfeiture of the performance Bank Guarantee for AMC.
VI. The contractor shall send his claim for payment in writing, when contractually due, along with relevant documents etc., duly signed with date, to the Client.
VII. The Performance Bank Guarantee/ Security Deposit submitted by the vendor shall be returned only on entering into the AMC agreement and on receipt of BG for AMC security. However, entering into an agreement on AMC with the Contractor is the sole discretion of the Client.

Name_____

Business Address_____

Place: _____ **Signature of Tenderer**_____

Date: _____ **Seal of the Tenderer**_____

SECTION – XI D PRICE SCHEDULE

PRICE SCHEDULE FOR TURNKEY (IF ANY)

Schedule No.	BRIEF TURNKEY (IF ANY) DESCRIPTION OF GOODS	Turnkey (if any) price

Note: -

1. The cost of Turnkey (if any) as per Technical Specification (Section VII) may be quoted on lump sum inclusive of all taxes & duties. Cost of Turnkey (if any) will be added for Ranking/Evaluation purpose.
2. The payment of Turnkey (if any) will be made as per clause GCC clause 21.1 (c).
3. The stipulations in Technical Specification will supersede above provisions

Name_____

Business Address_____

Place:_____ **Signature of Tenderer**_____

Date:_____ **Seal of the Tenderer**_____

SECTION – XII

QUESTIONNAIRE

Fill up the Section XIX – Check List for Tenderers and enclose with the Tender

1. The tenderer should furnish specific answers to all the questions/issues mentioned in the Checklist. In case a question/issue does not apply to a tenderer, the same should be answered with the remark “not applicable”
2. Wherever necessary and applicable, the tenderer shall enclose certified copy as documentary proof/ evidence to substantiate the corresponding statement.
3. In case a tenderer furnishes a wrong or evasive answer against any of the question/issues mentioned in the Checklist, its tender will be liable to be ignored.

SECTION – XIII

BANK GUARANTEE FORM FOR EMD

Whereas _____ (hereinafter called the "Tenderer") has submitted its quotation dated _____ for the supply of _____ (hereinafter called the "tender") against the purchaser's tender enquiry No. _____ Know all persons by these presents that we _____ of _____ (Hereinafter called the "Bank") having our registered office at _____ are bound unto _____ (hereinafter called the "Purchaser) in the sum of _____ for which payment will and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this _____ day of _____ 20____. The conditions of this obligation are:

(1) If the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.

(2) If the Tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity:-

a) fails or refuses to furnish the performance security for the due performance of the contract.
or
b) fails or refuses to accept/execute the contract.
or
c) if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged

We undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition(s).

This guarantee will remain in force for a period of forty-five days after the period of tender validity and any demand in respect thereof should reach the Bank not later than _____ day of _____ 20____..

(Signature of the authorised officer of the Bank)

Name and designation of the officer

Seal, name & address of the Bank and address of the Branch

SECTION – XIV

MANUFACTURER'S AUTHORISATION FORM

To

HLL Biotech Limited, Chennai

Dear Sirs,

Ref. Your TE document No _____, dated _____

We, _____ who are proven and reputable manufacturers of_____(*name and description of the goods offered in the tender*) having factories at_____, hereby authorise Messrs_____(*name and address of the agent*) to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs. _____ (*name and address of the above agent*) is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, AMC Support as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we shall be overall responsible for the timely delivery of the equipment ,installation, testing, commissioning and validation as per the requirements stipulated and agreed in the Tender Enquiry document.

Yours faithfully,

[*Signature with date, name and designation*]
for and on behalf of Messrs_____

[*Name & address of the manufacturers*]

Note:

1. *This letter of authorisation should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.*
2. *Original letter may be sent.*

SECTION – XV (A)

BANK GUARANTEE FORM FOR ADVANCE BANK GUARANTEE

Ref.....

Date.....
Bank Guarantee No....

To

HLL Biotech Ltd.,
Module 013-015,
Ticel Biopark Campus,
CSIR Road, Taramani,
Chennai – 600 113.

Dear Sirs,

In consideration of the HLL Biotech Ltd., hereinafter referred to as 'HBL', which expression shall unless repugnant to the context or meaning thereof include its successors, executors, administrators and assigns, having awarded to M/s._____ having its registered office at _____
hereinafter referred as the 'Supplier', which expression shall unless repugnant to the context or meaning thereof, include its successors, Administrators, executors and assigns, a contract hereinafter referred to as the 'Order' for _____ referred to as the 'Supply and Services' on terms and conditions set out, inter-alia in the HBL's Order No. _____ dated _____valued _____at (in words & figures) and as the HBL having agreed to make a payment against the above ORDER, to the Supplier amounting to Rs. _____(in words & figures) as an advance against Bank Guarantee to be furnished by the Supplier, the said advance to be adjusted against the supply and services to be performed by the Supplier, we _____ hereinafter referred to as the 'Bank' which expressions shall, unless repugnant to the context or meaning thereof, include its successors, administrators, executors and assigns **having our office at _____do hereby undertake to give the irrevocable and unconditional guarantee and** do hereby undertake to pay the HBL on first demand without any demur, **reservation, contest recourse and protest and without reference to the Supplier** any and all monies payable by the Supplier by reason of any breach by the said Supplier of any of the terms and conditions of the said order to the extent of Rs. _____ (in words & figures) till the said advance is adjusted as aforesaid at any time up to _____.We agree that the guarantee herein contained shall continue to be enforceable till the sum due to the HBL on account of the said advance is adjusted/recovered in full as aforesaid or till the HBL discharges this guarantee.

The HBL shall have the fullest liberty without affecting in any way the liability of the Bank under this guarantee, from time to time vary the advance or to extend the time for performance of the supply and services by the Supplier. The Bank shall not be released from its liability under these presents by any exercise of the HBL of the liberty with reference to the matter aforesaid.
The HBL shall have the fullest liberty, **without reference to Supplier and** without affecting this guarantee to post-pone **for any time or** from time to time the exercise of any powers vested in them or of any right which they might have against the Supplier, and to exercise the same at any time in any manner, and either to enforce or to forebear to enforce any **power**, covenants contained or implied in the order between the HBL and the Supplier or any other course or remedy or security available to the HBL and the Bank shall not be released of its obligations under these presents by any exercise by the HBL of its liberty with reference to matters aforesaid or any of them or by reason of any other act or forbearance or other acts of omission or commission on the part of the HBL or any other

indulgence shown by the HBL or by any other matter or thing whatsoever which under law would, but for this provision, have the effect of relieving the Bank Guarantee.

The right of HBL to recover the outstanding sum of advance with applicable costs up to Rs._____ from the bank in the manner aforesaid will not be affected or suspended by reason of the fact that any dispute or disputes is or are pending before any officer, tribunal or court and any demand made by HBL on the Bank shall be conclusive and binding.

The Bank further undertakes not to revoke this guarantee during its currency without prior and written consent of the **HBL and further agrees that the guarantee contained shall continue to be enforceable till the HBL discharges this guarantee.**

The Bank also agrees that the HBL shall at its option is entitled to enforce this guarantee against the bank as principal debtors, in first instance, notwithstanding any other security or guarantee that **HBL** may have in relation to the Supplier's liabilities of the said advance.

Notwithstanding anything contained herein above, our liability under this guarantee is restricted to as Rs. _____(in words & figures) and it will remain in force up to and including _____(date of completion of supply and services) and shall be extended from time to time for such periods as may be advised by M/s…… on whose behalf this guarantee has been given.

Therefore, we hereby affirm that we are guarantors and responsible to you on behalf of the Supplier up to a total amount of _____(amount of guarantees in words and figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the purchase order and without caveat or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or show grounds or reasons for your demand or the sum specified therein.

This Guarantee is valid until _____ day _____.

We have power to issue this guarantee in your favour under Memorandum and Articles of Association and the undersigned has full power to do under the Power of Attorney / Resolution of Board of Directors dated.....granted to him by the Bank.

Dated.....this.....day of.....20

Signed by

Place:

(Person duly authorised by Bank)

Witness :

SECTION – XV (B)

BANK GUARANTEE FORM FOR PERFORMANCE SECURITY

To

HLL Biotech Ltd.,
Module 013-015,
Ticel Biopark Campus,
CSIR Road, Taramani,
Chennai – 600 113.

1. In consideration of HLL Biotech Limited (hereinafter called "HBL") having agreed under the terms and conditions of Order No…….. dated……. made between ……. (here in after called "the said contractor(s)") for the …….. work (herein after called "the said agreement") for compliance of his obligation in accordance with the terms and conditions in the said agreement.

We …….. (indicate the name of the Bank) (herein after referred to as "as Bank) hereby undertake to pay to the HBL and amount not exceeding Rs….. (Rupees…….. only) on demand by HBL.

2. We …….. (Indicate the name of the Bank) do hereby undertake to pay the amount due and payable under this Guarantee without any demure, merely on a demand from HBL stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). any such demand made on the Bank shall be conclusive as regards the amount due and payable by the bank under this Guarantee. However, our liability under this guarantee shall be restricted to an amount not exceeding Rs……. (Rupees……. only).

3. We undertake to pay to HBL any money so demanded notwithstanding any dispute or disputes raised by the contractor (s) in any suit or proceeding pending before any court or Tribunal relating thereto our liability under this present being absolute and unequivocal.

The payment made by us under this guarantee shall be valid discharge of our liability for payment to there-under and the contractor(s) shall have no claim against us making such payment.

4. We …….. (Indicate the name of Bank) further agree that the guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement and that it shall continue to be enforceable till all the dues of HBL under or by virtue of the said agreement have been fully paid and its claims satisfied or discharged or till Engineer-in-charge on behalf of HBL Certified that the terms and conditions of the said Agreement have been fully and properly carried out by the said contractor(s) accordingly discharges this guarantee.

5. We…….. (Indicate the name of Bank) further agree with HBL that HBL shall have the fullest liberty without our consent and without affecting any manner our obligations hereunder to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time or to postpone for any of the powers exercisable by HBL against the said contractor(s) and to forebear or enforce any of the terms and conditions relating to the said agreement we shall not be relieved from our liability by reasons of any such variation or extension being granted to the said contractor(s) or for any forbearance act of omission on that part of the HBL or any indulgence by HBL to the said contract(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effected or so relieving us.

6. The guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).

7. We……. (indicate the name of Bank) lastly undertake not to revoke this guarantee except with the previous consent of HBL in writing.

8. This guarantee shall be valid up to …….. unless extended on demand by HBL. Notwithstanding anything mentioned above our liability against this Guarantee is restricted to Rs……. (Rupees……only) and unless a claim in writing is lodged with us within six months of the date of expiry or the extended date of expiry of this guarantee, all our liabilities under the Guarantee shall stand discharged.

Dated the …….. day of 20….

For ……
(Indicate the name of Bank)

……

Seal, name & address of the Bank and address of the Branch

SECTION – XVI

CONTRACT FORM - A

CONTRACT FORM FOR SUPPLY, INSTALLATION, COMMISSIONING, VALIDATION, HANDING OVER, TRIAL RUN, TRAINING OF OPERATORS & WARRANTY OF GOODS

HLL Biotech Limited

Contract No_____ dated_____

This is in continuation to this office's Notification of Award No_____ dated _____

1. Name & address of the Supplier: _____
2. Purchaser's TE document No_____ dated_____ and subsequent Amendment No_____, dated_____ (if any), issued by the purchaser
3. Supplier's Tender No_____ dated_____ and subsequent communication(s) No_____ dated _____ (if any), exchanged between the supplier and the purchaser in connection with this tender.
4. In addition to this Contract Form, the following documents etc, which are included in the documents mentioned under paragraphs 2 and 3 above, shall also be deemed to form and be read and construed as integral part of this contract:

   (i) General Conditions of Contract;
   (ii) Special Conditions of Contract;
   (iii) List of Requirements;
   (iv) Technical Specifications;
   (v) Quality Control Requirements;
   (vi) Tender Form furnished by the supplier;
   (vii) Price Schedule(s) furnished by the supplier in its tender;
   (viii) Manufacturers' Authorisation Form (if applicable for this tender);
   (ix) Purchaser's Notification of Award

Note: The words and expressions used in this contract shall have the same meanings as are respectively assigned to them in the conditions of contract referred to above. Further, the definitions

and abbreviations incorporated under clause 1 of Section II – 'General Instructions to Tenderers' of the Purchaser's TE document shall also apply to this contract.

5. Some terms, conditions, stipulations etc. out of the above-referred documents are reproduced below for ready reference:

    (i) Brief particulars of the goods and services which shall be supplied/ provided by the supplier are as under:

Schedule No.	Brief description of goods/services	Accounting unit	Quantity to be supplied	Unit Price	Total price	Terms of delivery

Any other additional services (if applicable) and cost thereof: _____

Total value (in figure) _____ (In words) _____

1. Delivery schedule

    (i) Details of Performance Security

    (ii) Quality Control

        (a) Mode(s), stage(s) and place(s) of conducting inspections and tests.
        (b) Designation and address of purchaser's inspecting officer

    (iii) Destination and despatch instructions

    (iv) Consignee, including port consignee, if any

2. Warranty clause
3. Payment terms
4. Paying authority

_____

(Signature, name and address of CONSIGNEE)

For and on behalf of_____

Received and accepted this contract

_____

(Signature, name and address of the supplier's executive duly authorised to sign on behalf of the supplier)
For and on behalf of _____

(Name and address of the supplier)

(Seal of the supplier)

Date: _____

Place: _____

SECTION – XVI

CONTRACT FORM – B

CONTRACT FORM ANNUAL MAINTENANCE CCONTRACT

AMC No._____ **dated**_____

Between

_____

_____

CONSIGNEE
And

_____

_____

(Name & Address of the Supplier)

Ref: **Contract No**_____ **dated**_____ **(Contract No. & date of Contract for supply, installation, commissioning, validation, handing over, Trial run, Training of operators & warranty of goods)**

In continuation to the above referred contract

2. The Contract for AMC is hereby concluded as under: -

1	2	3	4		5
Schedule No.	**BRIEF DESCRIPTION OF GOODS**	**QUANTITY. (Nos.)**	**Annual Maintenance Contract Cost for Each Unit year wise*.**		**Total Annual Comprehensive Maintenance Contract Cost for 2 Years [3 x (4A+4B)]**
			1st	**2nd**	
			A	**B**	

Total value (in figure) _____ (In words) _____

b) The AMC commence from the date of expiry of all obligations under Warranty i.e. from_____ (date of expiry of Warranty) and will expire on _____ (till end of AMC period i.e 2 years)

c) The cost of AMC which includes calibration of the Equipment along with Calibration Certificate, the necessary calibration tools, labour charges as per technical/ service /operational manual of the manufacturer, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any). The authorized Technical person to be deputed for AMC.

_____ (name of the consignee)

_____

(Signature, name and address of Consignee)

For and on behalf of_____

Received and accepted this contract

(Signature, name and address of the supplier's executive
duly authorised to sign on behalf of the supplier)

For and on behalf of _____
(Name and address of the supplier)

(Seal of the supplier)

Date: _____

Place: _____

SECTION – XVII

PROFORMA OF CONSIGNEE RECEIPT CERTIFICATE

(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) Contract No. & date :_____

2) Supplier's Name :_____

3) Consignee's Name & Address with telephone No. & Fax No. : _____

4) Name of the item supplied :_____

5) Quantity Supplied :_____

6) Date of Receipt by the Consignee :_____

7) Name and designation of Authorized Representative of Consignee :_____

8) Signature of Authorized Representative of Consignee with date :_____

9) Seal of the Consignee :_____

SECTION – XVIII

Proforma of Final Acceptance Certificate by the Consignee

No_____

Date_____

To

M/s _____
_____
_____

Subject: Certificate of commissioning of equipment/plant.

This is to certify that the equipment(s)/plant(s) as detailed below has/have been received in good conditions along with all the standard and special accessories and a set of spares (subject to remarks in Para no.02) in accordance with the contract/technical specifications. The same has been installed and commissioned.

(a) Contract No_____ dated_____

(b) Description of the equipment(s)/plants: _____

(c) Equipment(s)/ plant(s) nos.:_____

(d) Quantity: _____

(e) Bill of Loading/Air Way Bill/Railway Receipt/ Goods Consignment Note no_____ dated _____

(f) Name of the vessel/Transporter:_____

(g) Name of the Consignee:_____

(h) Date of commissioning and proving test:_____

Details of accessories/spares not yet supplied and recoveries to be made on that account.

Sl. No.	Description of Item	Quantity	Amount to be recovered

The proving test has been done to our entire satisfaction and operators have been trained to operate the equipment(s)/plant(s).

The supplier has fulfilled its contractual obligations satisfactorily ## or

The supplier has failed to fulfill its contractual obligations with regard to the following:

- He has not adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specifications'.
- He has not supervised the commissioning of the equipment(s)/plant(s)in time, i.e. within the period

specified in the contract from date of intimation by the Purchaser/Consignee in respect of the installation of the equipment(s)/plant(s).

- The supplier as specified in the contract has not done training of personnel.

The extent of delay for each of the activities to be performed by the supplier in terms of the contract is:

The amount of recovery on account of non-supply of accessories and spares is given under Para no.02.

The amount of recovery on account of failure of the supplier to meet his contractual obligations is_____ (here indicate the amount).

Signature
Name
Designation with stamp

Explanatory notes for filling up the certificate:

He has adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specification'.

He has supervised the commissioning of the equipment(s)/plant(s) in time, i.e. within the time specified in the contract from date of intimation by the Purchaser/Consignee in respect of the installation of the equipment(s)/plant(s).

Training of personnel has been done by the supplier as specified in the contract
In the event of documents/drawings having not been supplied or installation and commissioning of the equipment(s)/plant(s) having been delayed on account of the supplier, the extent of delay should always be mentioned in clear terms.

SECTION – XIX

CHECKLIST

NAME OF TENDERER:

NAME OF MANUFACTURER:

Sl No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
1. a.	Have you enclosed EMD of required amount for the quoted schedules?			
b.	In case EMD is furnished in the form of Bank Guarantee, has it been furnished as per Section XIII?			
c.	In case Bank Guarantee is furnished, have you kept its validity of 165 days from Techno-Commercial Bid Opening date as per clause 18 of GIT?			
2. a.	Have you enclosed duly filled Tender Form as per format in Section X?			
b.	Have you enclosed Power of Attorney in favour of the signatory?			
3.	Are you a SSI unit, if yes have you enclosed certificate of registration issued by Directorate of Industries/NSIC			
4. a.	Have you enclosed clause-by-clause technical compliance statement for the quoted goods vis-à-vis the Technical specifications?			
b.	In case of Technical deviations in the compliance statement, have you identified and marked the deviations?			
5. a.	Have you submitted satisfactory performance certificate as per the Proforma for performance statement in Sec. IX of TE document in respect of all orders?			
b.	Have you submitted copy of the order(s) and end user certificate?			
6.	Have you submitted manufacturer's authorization as per Section XIV?			
7.	Have you submitted prices of goods, turnkey (if any), AMC etc. in the Price Schedule as per Section XI?			
8.	Have you kept validity of 120 days from the Techno-Commercial Bid Opening date as per the TE document?			

Sl No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
9. a.	In case of Indian Tenderer, have you furnished Income Tax Account No. as allotted by the Income Tax Department of Government of India?			
b.	In case of Foreign Tenderer, have you furnished Income Tax Account No. of your Indian Agent as allotted by the Income Tax Department of Government of India?			
10.	Have you intimated the name and full address of your Banker (s) along with your Account Number			
11.	Have you fully accepted payment terms as per TE document?			
12.	Have you fully accepted delivery period as per TE document?			
13.	Have you submitted the certificate of origin			
14.	Have you accepted the warranty as per TE document?			
15.	Have you accepted terms and conditions of TE document?			
16.	Have you furnished documents establishing your eligibility & qualification criteria as per TE documents?			
17	Have you furnished Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening?			
18	Have you signed and sealed the Integrity Pact as per section XXI of the tender			
19	Have you enclosed the DD/Bankers cheque for the tender fee?			

N.B.

1. All pages of the Tender should be page numbered and indexed.
2. The Tenderer may go through the checklist and ensure that all the documents/confirmations listed above are enclosed in the tender and no column is left blank. If any column is not applicable, it may be filled up as NA.
3. It is the responsibility of tendered to go through the TE document to ensure furnishing all required documents in addition to above, if any.

(Signature with date)

(Full name, designation & address of the person duly authorised sign on behalf of the Tenderer)
For and on behalf of

(Name, address and stamp of the tendering firm)

Section – XX

Consignee

All Goods shall be delivered at

INTEGRATED VACCINES COMPLEX

HLL BIOTECH LIMITED

SF No: 192 & 195

Thirumani Village

Chengalpattu - 603001

Tamil Nadu

India.

SECTION – XXI

To be signed by the bidder and same signatory competent/authorized to sign the relevant contract of behalf of HLL Biotech Limited

INTEGRITY AGREEMENT

This Integrity Agreement is made at …… on this ……. Day of……..20…….

BETWEEN

President of India represented through Chief Executive Officer, HLL Biotech Limited (Hereinafter referred as the "Principal/Owner", which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns.

AND

…….
through …….. (Hereinafter referred to as the **"Bidder/Contractor**" and which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns).

Preamble

WHEREAS the Principal / owner has floated the Tender (NIT No……..)
(Hereinafter referred to as "**Tender/Bid**") and intends to award, under laid down organizational procedure, contract for ……
Hereinafter referred to as the **"Contract"**

AND WHEREAS the Principal /Owner values full compliance with all relevant laws of the land, rules, regulations, economic use of resources and of fairness/transparency in its relation with its Bidder(s) and Contractor(s).

AND WHEREAS to meet the purpose aforesaid both the parties have agreed to enter into this Integrity Agreement (hereinafter referred to as **"Integrity Pact**" or **" Pact**"), the terms and conditions of which shall also be read as integral part and parcel of the Tender Bid documents and Contract between the parties. NOW, THEREFORE, in consideration of mutual covenants' contained in this Pact, the parties hereby agree as follows and this Pact witnesses as under:

Article 1: Commitment of the Principal /Owner

1) The Principal /Owner commits itself to take all measures necessary to prevent corruption and to observe the following principles.

   (a) No employee of the Principal/Owner, personally or through any of his/her family members, will in connection with the Tender, or the execution of the Contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.

   (b) The Principal/Owner will, during the Tender process, treat all Bidder(s) with equity and reason. The Principal/owner will, in particular, before and during the Tender process, provide to all Bidder(s) the same information and will not provide to any Bidder(s) confidential / additional information through which the Bidder (s) could obtain an advantage in relation to the Tender process or the Contract execution.

(c) The Principal /Owner shall Endeavour to exclude from the Tender process any person, whose conduct in the past has been of biased nature.

2) If the Principal/Owner obtains information on the conduct t of any of its employees which is a criminal offence under the Indian Penal code (IPC)/Prevention of Corruption Act, 1988 (PC Act) or is in violation of the principles herein mentioned or if there be a substantive suspicion in this regard, the Principal/Owner will inform the Chief Vigilance Officer and in addition can also in initiate disciplinary actions as per its internal laid down policies and procedures.

Article 2: Commitment of the Bidder(s) / Contractor(s)

1) It is required that each Bidder/Contractor(including their respective officers, employees and agents) adhere to the highest ethical standards, and report to the Government/Department all suspected acts of **fraud or corruption or Coercion or Collusion** of which it has knowledge or becomes aware, during the tendering process and throughout the negotiation or award of a contract.

2) The Bidder(s)/Contractor(s) commit himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the Tender process and during the Contract execution.

(a) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm, offer, promise or give to any of the Principal/owner's employees involved in the Tender process or execution of the Contract or to any third person any material or other benefit which he/she which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the Tender process or during the execution of the Contract.

(b) The Bidder(s) will not enter with other Bidder(s) into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certification, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to cartelize in the bidding process.

(c) The Bidder(s)/Contractor(s) will not commit any offence under the relevant IPC/PC Act. Further the Bidder(s) /Contract(s) will not use improperly, (for the purpose of competition or personal gain).or pass on to others, any information or documents provided by the Principal/Owner as part of the business relationship, regarding plans, technical proposals and business details, including and business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.

(d) The Bidder (s) /Contractor (s) of foreign origin shall disclose the names and addresses of agents/representatives in India, if any Similarly Bidder(s)/Contractor(s) of Indian Nationality shall disclose names and addresses of foreign agents/representatives, if any. Either the Indian agent on behalf of the foreign principal or the foreign principal directly could bid in a tender but not both. Further, in cases where an agent participate in a tender on behalf of one manufacturer, he shall not be allowed to quote on behalf of another manufacturer along with the first manufacturer in a subsequent/parallel tender for the same item.

(e) The Bidder (s)/Contractor (s) will , when presenting his bid, disclose (with each tender as per proforma unclosed) any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the Contract.

3) The Bidder(s) /Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.

4) The Bidder (s)/contractor(s) will not, directly or through any other person or firm indulge in fraudulent practice means a willful misrepresentation or omission of facts or submission of fake/forged documents in order to induce public official to act in reliance thereof, with the purpose of obtaining unjust advantage by or causing damage to justified interest of others and /or to influence the procurement process to the detriment of the Government interests.

5) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm use Coercive Practices (Means the act of obtaining something, compelling an action or influencing a decision through intimidation, threat or the use of force directly or indirectly, where potential or actual injury may befall upon a person, his/her reputation or property to influence their participation in the tendering process).

Article 3: Consequences of Breach

Without prejudice to any rights that may be available to the Principal/Owner under law or the Contract or its established policies and laid down procedures, the Principal/Owner shall have the following rights in case of breach of this integrity Pact by the Bidder (s)/Contractor(s) and the Bidder(s)/Contractor(s) accepts and undertakes to respect and uphold the Principal /Owner's absolute right:

1) If the Bidders) / Contractor(s), either before award or during execution of Contract has committed a transgression through a violation of Article 2 above or in any other form, such as to put his reliability or credibility in question, the Principal/owner after giving 14 days notice to the contractor shall have powers to disqualify the Bidder (s)/Contractor(s) from the Tender process or terminate/determine the Contract, if already executed or exclude the Bidder/Contractor from future contract award processes. The imposition and duration of the exclusion will be determined by the severity of transgression and determined by the Principal/owner. **Such exclusion may be forever or for a limited period as decided by the Principal/owner.**

2) **Forfeiture of EMD/performance Guarantee/Security Deposit:** If the Principal/owner has disqualified the Bidder(s) from the Tender process prior to the award of the Contract or terminated/determined the Contract or has accrued the right to terminate/determine the Contract according to Article 3(1), the Principal /Owner apart from exercising any legal rights that may have accrued to the Principal/Owner, may in its considered opinion forfeit the entire amount of Earnest Money Deposit, Performance Guarantee and security Deposit, Performance Guarantee and security Deposit of the Bidder/Contractor.

3) **Criminal Liability**: If the Principal/Owner obtains knowledge of conduct of a Bidder or Contractor, or of and employee or a representative or an associate of a Bidder or Contractor which constitutes corruption within the meaning of Indian Penal code (IPC)/Prevention of corruption Act, or if the Principal/owner has substantive suspicion in this regard, the Principal/owner will inform the same to low enforcing agencies for further. Investigation.

Article 4- Previous Transgression

1) The Bidder declares that no previous transgressions occurred in the last 2 years with any other Company in any country confirming to the anticorruption approach or with Central Government or State Government or any other Central/State Public sector Enterprises in India that could justify his exclusion from the Tender process.

2) If the Bidder makes incorrect statement on this subject, he can be disqualified from the Tender process or action can be taken for banning of business dealings/ holiday listing of the Bidder/Contractor as deemed fit by the Principal/owner.

3) If the Bidder/Contractor can prove that he has resorted / recouped the damage caused by him and has installed a suitable corruption prevention system, the Principal/owner may, at its own discretion, revoke the exclusion prematurely.

Article 5- Equal Treatment of all Bidders/Contractors/Subcontractors

1) The Bidder(s) /Contractor(s) undertake(s) to demand from all subcontractors a commitment in conformity with this Integrity Pact. The Bidder/Contractor shall be responsible for any violation(s) of the principles laid down in this agreement /pact by any of its Sub-contractors/sub-vendors.

2) The Principal/owner will enter into Pacts on identical terms as this one with all Bidders and Contractors.

Article 6- Duration of the Pact

This Pact begins when both the parties have legally signed it. It expires for the Contractor/Vendor 12 months after the completion of work under the contract or till the continuation of defect Liability period, whichever is more and for all other bidders, till the Contract has been awarded.

If any claim is made/lodged during the time, the same shall be binding and continue to be valid despite the lapse of this Pacts as specified above, unless it is discharged /determined by the competent authority, HLL Biotech Limited.

Article 7- other Provisions

1) This Pact is subject to Indian Law., place of performance and jurisdiction is the Head quarters of HLL Biotech Limited of the Principal/Owner, who has floated the Tender.

2) Changes and supplements need to be made in writing. Side agreements have not been made.

3) If the Contractor is a partnership or a consortium, this Pact must be signed by all the partners or by one or more partner holding power of attorney signed by all the partners or by one or more partner holding power of attorney signed by all partners and consortium members. In case of a company, the Pact must be signed by a representative duly authorized by board resolution.

4) Should one or several provisions of this Pact turn out to be invalid; the remainder of this Pact remains valid. In this case, the parties will strive to come to an agreement to their original intensions.

5) It is agreed term and condition that any dispute or difference arising between the parties with regard to the terms of this Integrity Agreement/pact, any action taken by the Owner/Principal in accordance with this **Integrity Agreement/Pact or interpretation thereof shall not be subject to arbitration.**

Article 8- LEGAL AND PRIOR RIGHTS:

All rights and remedies of the parties hereto shall be in addition to all the other legal rights and remedies belonging to such parties under the Contract and /or law and the same shall be deemed to be cumulative and not alternative to such legal rights and remedies aforesaid. For the sake of brevity, both the Parties agree that this Integrity Pact will have precedence over the Tender /Contact documents with regard any of the provisions covered under this Integrity Pact.

IN WITNESS WHERE OF the parties have signed and executed this Integrity Pact at the place and date first above mentioned in the presence of following witnesses:

……
(For and on behalf of Principal/owner)

……
(For and on behalf of Bidder/Contractor)

WITNESSES:

1.

(Signature, Name & address)

2.

(Signature, Name & address)

Place:

Date:

Section XXII

Instruction of Ministry of Shipping & Transport, New Delhi, India

1. DETAILS OF SHIPPING ARRANGEMENT FOR LINER CARGOES IN RESPECT OF C & F/CIF/TURNKEY/F.O.R CONTRACTS FOR IMPORTS

(a) SHIPMENT FROM PORTS OF U.K INCLUDING NORTHERN IRELAND (ALSO EIRE), FROM THE NORTH CONTINENT OF EUROPE (GERMANY, HOLLAND, BELGIUM, FRANCE, NORWAY, SWEDEN, DENMARK, FINLAND AND PORTS ON THE CONTINENTAL SEABOARD OF MEDITERRANIAN (I.E. FRENCH WESTERN ITALIAN PORTS), TO PORTS IN INDIA.

The Seller should arrange shipment of the goods by vessels belonging to the member lines of the India-Pakistan-Bangladesh Conference. If the Seller finds that the space on the „Conference Lines" vessels is not available for any specific shipment, he should take up with India-Pakistan-Bangladesh Conference. Conferity House, East Grinstead, Sussex (UK), for providing shipping space and also inform the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159) The Seller should arrange shipment through the Government of India"s Forwarding Agents, M/s Schenker & Co., 2000-Hamburg (Cable: SCHENKER CO., HAMBURG) OR obtain a certificate from them to the effect that shipment has been arranged in accordance with instructions of the Ministry of Surface Transport, (TRANSCHART), New Delhi.

(b) SHIPMENT FORM PORTS OF U.K. INCLUDING NORTHERN Goods under this contract would be shipped by the national shipping companies of the Contracting Parties operating bilateral shipping service and vessels under the flag of third countries in accordance with the Agreement between the Government of German Democratic Republic and the Government of the Republic of India in the Field of Merchant Shipping signed on 9.1.1979, as amended up-to-date.

(c) ISHIPMENT FROM ADRIATIC PORTS OF EASTERN ITALY AND YUGOSLAVIA The seller should arrange shipment of the goods by vessels belonging to the following Indian member lines;

1. The Shipping Purchaser of India Ltd.

2. The Scindia Steam Navigation Co., Ltd

3. India Steamship Co., Ltd

For the purpose of ascertaining the availability of suitable Indian vessels and granting dispensation in the event of their non-availability, the Seller should give adequate notice about the readiness of each consignment from time to time at least six weeks in advance of the required position to M/s Schenker & Co. 2000 HAMBURG (Cable: SCHENKER CO., HAMBURG) and also endorse a copy thereof to the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159)

The seller should arrange shipment through the Government of India"s Forwarding Agents M/s Schenker & Co. 2000 HAMBURG (Cable: SCHENKER CO., HAMBURG) or obtain certificate from them to the effect that shipment has been arranged in accordance with the instructions of the Ministry of Surface Transport, (TRANSCHART), New Delhi.

(d) SHIPMENT FROM POLAND & CZECHOSLOVAKIA

(i) IMPORTS FROM POLAND

Shipment under this contract would be made by the National flag lines of the two parties and vessels of the third flag conference lines, in accordance with the agreement between the Govt. of the Republic of India and

the Govt. of the Polish People"s Republic regarding Shipping Co-operation dated 27.6.1960 as amended up-to-date.

(ii) IMPORTS FROM CZECHOSLOVAKIA

Goods under this contract would be signed by the National flag lines of the two parties and vessels of the third flag conference lines, in accordance with the Agreement Co-operation in shipping between India and Czechoslovakia signed on 3.11.1978 and ratified on 19.12.1979, as amended up-to-date. Shipping arrangement should be made by the Sellers in consultation with Resident Representative of the Indian Shipping Lines in Gdynia, Co., Morska Agencja W. Gdyniul, Pulaskiego 8, P.O. Box 246, Gdynia (Poland) – Telex : MG PL. 054301, Tel.: 207621, to whom details regarding contract number, nature of cargo , quantity, port of lading, discharging, name of Government consignee, expected date of readiness of each consignment etc. should be furnish at least six weeks in advance of the required position, with a copy thereof endorsed to the Shipping Co-ordination Officer, Ministry of Surface Transport, (Chartering Wing), New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159)

(e) SHIPMENT FROM U.S.S.R Shipment under this contract should be made in accordance with the agreement between the Government of the Republic of India and the Government of U.S.S.R on Merchant Shipping 1976, as amended up-to-date, by vessels of Indo-Soviet shipping Service.

(f) SHIPMENT FROM JAPAN The shipment of goods should be made of India vessels to the maximum extent possible subject to the minimum of 50%. The Seller should arrange shipment of the goods in consultation with the Embassy of India in Japan, Tokyo to whom details regarding contract number, nature of cargo, quantity, port of loading/discharge, name of Govt. consignee, expected date of readiness of each consignment etc. should be furnished at least six weeks in advance of the required position. Note: The copies of such contracts are to be endorsed both to the Attached (commercial) embassy of India in Japan, Tokyo, and the shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi.

(g) SHIPMENT FROM AUSTRALIA, ALGERIA, BULGARIA, ROMANIA, EGYPT HLL Biotech Limited

The Seller shall arrange shipment of the goods by Indian flag vessels to the maximum extent possible subject to a minimum of 50 %. For the purpose of ascertaining the availability of suitable Indian vessels, the seller shall give adequate notice of not less than six weeks about the readiness of each consignment to the Shipping Purchaser of India Ltd., SHIPPING HOUSE, 245, Madame Cama Road, Bombay – 400 021 (CABLE: SHIPINDIA BOMBAY) and also endorse a copy thereof to the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159)

(h) SHIPMENT FROM PAKISTAN The shipment of cargoes should be made by Indian vessels to the maximum extent possible subject to a minimum of 50 %. Shipment arrangement should be made by the sellers in consultation with M/s Mogul Line Ltd., 16-Bank Street, Fort, Bombay – 400023 (Cable: MOGUL BOMBAY: Telex: 011 – 4049 MOGUL), to whom, details regarding contract number, nature of cargo, quantity, port of lading discharging, name of government consignee, expected date of readiness of each consignment etc. should be furnish at least six weeks in advance of the required position, with a copy thereof endorsed to the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159)

(i) SHIPMENT FROM U.S ATLANTIC & GULF PORTS The Seller should arrange shipment of the goods by vessels belonging to the member lines of the India – Pakistan – Bangladesh – Ceylon and Burma Outward Freight Conference. If the Seller finds that the space of the „Conference Lines" vessels is not available for any specific shipment he should take up with India – Pakistan- Bangladesh – Ceylon and Burma Outward Freight Conference, 19, Rector Street, New York, N.Y. 10006 USA, for providing shipping space and also inform the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159)

(i) SHIPMENT FROM ST. LAWRENCE AN EASTERN CANADIAN PORTS The Seller should arrange shipment of the goods by vessels belonging to the following shipping lines;

1. The shipping Purchaser of India Ltd.

2. The Scindia Steam Navigation Co., Ltd

If the Seller finds that the space in the vessels of these Lines is not available for any particular consignments, he should inform the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159) immediately so that dispensation from the shipping lines concerned to use alternative lifting may be sought.

(j) SHIPMENT FROM WEST COAST PORTS OF U.S. CANADA AND OTHER AREAS NOT SPECIFICALLY MENTIONED ABOVE

The Seller should arrange shipment of the goods by Indian vessels to the maximum extent possible subject to a minimum of 50 %. For the purpose of ascertaining the availability of suitable Indian vessels and granting dispensation in the event of their non-availability, the Seller should furnish the details regarding contract number, nature of cargo, quantity, port of lading, discharging, name of government consignee, expected date of readiness of each consignment etc. to the Shipping Co-ordination Officer, Ministry of Surface Transport, New Delhi, (Cable: TRANSCHART, NEW DELHI, Telex: VAHAN IN – 031 – 61157, 61158, 61159) at least six weeks in advance of the required position.

2. BILLS OF LADING:

(i) C.I.F./C&F/TURNKEY SHIPMENTS

The Bills of lading should be drawn to indicate Shipper and „Consignee" as under: SHIPPER: The C.I.F (C&F)/TURNKEY SUPPLIERS concerned. CONSIGNEE: As per consignee"s particulars in the contract (The name an address of the „Port Consignee" and „Ultimate" both should be indicated).

(ii) F.O.R SHIPMENTS

The Bills of lading should be drawn to indicate shipper Consignee as under: SHIPPER: The F.O.R suppliers Concerned CONSIGNEE: Supplier"s Indian Agent on order

Note:

1. Moreover the name of the „Purchaser" and „Ultimate" Consignee should appear in the body of the Bills of Lading as the „Notify" or as a remark.

2. Two non-negotiable copies of the Bills of Lading indicating the freight amount and discount, if any allowed, should be forwarded to The Shipping Co-ordination Officer, Ministry of surface Transport (Chartering Wing), New Delhi after the shipment of each consignment is effected.

3. The seller should avoid the use of over-aged vessels for the shipment of the goods under the contract and if so used the cost of additional. Insurance, if any, shall be borne by the seller.

Section XXIII

SCHEDULE OF FISCAL ASPECTS

Sr. No.	Particulars	Description
1.	Submission of completed Tender	26.12.2017 (For Sch I to X) 27.12.2017 (For Sch XI to X) 28.12.2017 (For Sch XXI to XXX) 29.12.2017 (For Sch XXXI to XLII) @ 11:00 Hrs
2.	Opening of Techno-Commercial Bid	26.12.2017 (For Sch I to X) 27.12.2017 (For Sch XI to X) 28.12.2017 (For Sch XXI to XXX) 29.12.2017 (For Sch XXXI to XLII) @ 11:30 Hrs
3.	Delivery	3 (Three) months from date of issue of Purchase Order
4.	Installation, commissioning and validation	1 (One) month from the delivery of the equipment at site.
5.	Advance	10% of the contract value against Bank Guarantee equivalent to 110% of the advance amount and submission of Security Deposit/ Performance Security of 5% of contract value from a Scheduled Commercial Bank. In case of Foreign tenderer, the bank guarantee shall be routed through a Scheduled Commercial Bank in India.
6.	Payment terms	As mentioned in GCC: Clause. 21
7.	Liquidated damages/per week	0.5% per week inclusive of Sundays & Holidays upto a maximum of 5% of Contract Value
8.	Warranty Period	12 (Twelve) months from the date of Completion.
9.	Earnest Money Deposit	As per Section-1(NIT)
10.	Refund of Earnest Money Deposit to unsuccessful bidders	On award of contract to successful bidder
11.	Insurance	Under Vendor's scope
12.	B.G/ DD to be in favor of	HLL Biotech Ltd., Chennai
13.	All queries / communication to be addressed to	The Chief Executive Officer HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113 Email:, ramanr@hllbiotech.com, sureshs@hllbiotech.com Contact No: 044 22544956/949/972 , Fax – 044 22540101

Sr. No.	Particulars	Description
14.	Pre-bid Meeting	04.12.2017 (For Sch I to X) 05.12.2017 (For Sch XI to XX) 06.12.2017 (For Sch XXI to XXX) 07.12.2017 (For Sch XXXI to XXIX) @ 11:00 Hrs **Venue:** **HLL Biotech Limited,** **Integrated Vaccine Complex,** **SF 192-195, Tirumani Village** **Chengalpattu -600 301**
(Contractor)		**(Employer)**

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Vortex mixer**

Document No.: DS-VOM 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	HiB	B1-VOM 02-03	-	2

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		31-05-2017
Checked by			
Mr. Yogesha M J	Engineer - Process	For T.S. Shete	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		08-06-2017
Project / Engineering department VISHNU. J	AM		16-06-2017
Approved by			
Head of the department MBB V. Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA)	Dept		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Vortex Mixer	
	Document No.: DS-VOM 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	Used to mix liquids to make homegenous suspensions.	
2	**Equipment ID**	
2.1	B1-VOM 02-03	
3	**Technical Specification**	
3.1	Model	cGMP compliant
3.2	Type	table top
3.3	Speed range	100 to 3200 rpm
3.4	Operating temperature	4 °C to 65 °C
3.5	Operating modes	yes
3.6	Touch mode	yes
3.7	Continious mode	yes
3.8	External Dimension (W x H x D) mm,	vendor to specify
3.9	Type of movement	Shaking / vortexing
3.10	Power Requirement	To be compatible to standard Indian Power supply
3.11	Permissible shaking weight	vendor to specify
3.12	Quantity	2 Nos.
3.13	Speed	Variable speed control allows slow speed shaking action up to high speed vortexing
4	**Material of Construction**	
4.1	Main body	Nitrile rubber
4.2	Head	Polyethylene
5	**Specific Equipment requirement**	
5.1	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	**Other requirement**	
6.1	Automatic press start, continuous run or touch activated run modes.	
6.2	Easy switch with optional heads to hold variety of test tubes. Rubber single cup tube holder and foam pad for mixing flasks or multiple tubes simultaneously.	
6.3	Equipment should have cold room / incubators compatibility and spill proof electronic use.	
6.4	Should be stable at high speeds	
6.5	Heavy duty cast metal base with rubber feet assures stability and eliminates creep during operation.	
6.6	Training / Demo for the users on operation and cleaning shall be considered	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Vortex Mixer	
	Document No.: DS-VOM 02	
	Revision No.: 00	

7	**Regulatory aspects**
7.1	CE Certification.
8	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
8.3	On power failure equipment should come in fail safe condition
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:
9.1	IOQ Document
9.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
9.3	Warranty letter for 1 year from the date of supply.
9.4	List of standard spare parts with ordering information.
9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	IKA, VELP Scientifica, Thermo, Spinix
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in m2	Room height in mm
G1-VOM-01-02	HiB	Polysaccharide Purification	BIG136	58	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Niharika Ruhela	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name:Table Top Cooling Centrifuge

Document No.: DS-TCC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	Hib	B1-TCC 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	30-05-2017
Checked by			
Ms. Yogesha MJ	Engineer - Process	For T.S.Shekar T.S.Shekar	30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		30-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		08-06-2017
Project / Engineering department VISHNU.S	AM	S.	16.06.2017
Approved by			
Head of the department: MBB Dr. Subrahmanyam M Murthy	Head-Bacterial Vaccines	M. V. Subrahmanyam	22-6-2017
Head of the department (QA) Dr. Suresh Babu	DGM	Dr. Suresh Babu	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Table Top Cooling Centrifuge	
	Document No.: DS-TCC 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	A table top centrifuge can be used to determine the wet mass of the fermentation culture for IPQC testing purpose .	
2	**Equipment ID**	
2.1	B1-TCC 02	
3	**Technical Specification**	
3.1	Model	cGMP model
3.2	Type	Table top cooling centrifuge
3.3	Temperature range	-10 °C to 40 °C
3.4	Temperature control	± 2 °C
3.5	Electrical Consumption	Vendor to specify
3.6	Speed range	Maximum speed 15,000 RPM (in 10 RPM increments)
3.7	Rotor included	Yes
3.8	Rotor capacity	48 positions for 1.5 ml / 2.0 ml with lid and 6 positions for 50 ml tubes including rotor lid.
3.9	Rotor	fixed Angle rotor
3.10	Quantity	1 No.
3.11	Power Requirement	To be compatible with standard Indian power supply socket.
3.12	Accuracy	± 10 rpm.
3.13	Control system	Microprocessor based with digital control
3.14	External Dimensions, (W x H x D)	Vendor to specify.
4	**Material of Construction**	
4.1	Outer body	Vendor to specify. The MOC of the outer body should be corrosion resistant and stain resistant
4.2	Rotor	Vendor to confirm
5	**Specific Equipment Requirements**	
5.1	Seamless, splash proof key pad with characteristic symbols should be provided for easy operation.	
5.2	Audible and optical alarms to indicate the end of operation and to indicate other abnormality conditions	
5.3	Rotor imbalance alarm should be given	
5.4	Warning measures for high and low temperature control.	
5.5	Hinged type top cover should be provided, that can be operated using single hand	
5.6	Electronic monitoring, to display the cause in case of any fault	
5.7	Cooling mechanism should be provided to maintain the uniform temperature throughout the Operation.	
5.8	The instrument should be designed for explosion-proof	

5.9	The cleaning shall be able to be done manually
5.10	On power failure the instrument should run under alternate power supply without interruption of the operation.
5.11	Low access height for easy loading and unloading of samples should be provided.
6	**Other Requirements**
6.1	LCD shall display the actual parameters: speed, time, relative centrifugal force
6.2	View ports for independent speed verification
6.3	Brushless motor-maintenance free
6.4	Rubber suction feet for stability
6.5	Timer: Up to 9 hours, 1 min to 99 minutes with continuous mode, short spin
6.6	Automatic rotor recognition to sense rotor type to set maximum allowable speed and with speed limitation for maximum safety.
6.7	Fast temperature function for fast pre-cooling.
6.8	Centrifuge lid with soft touch lid closer.
6.9	Standby cooling function holds temperature when centrifuge is not in use.
6.1	Suitable adapters shall be provided for different rotors.
6.11	Equipment shall be compatible for cleaning with all standard disinfectant.
6.12	Training/Demo for users on operation and cleaning to be provided
7	**Accessories required**
7.1	vender should be provided 1000 No. of 1.5 ml centrifuge tubes.
8	**Regulatory aspects**
8.1	CE certification
9	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
9.1	Always follow appropriate laboratory practices when using this equipment.
9.2	Appropriate closure of all parts.
9.3	On power failure equipment should come in fail safe condition and must retain the data.
9.4	Lid should not be possible to be opened while spinning
9.5	Noise level should not be more than 60 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.**
10.2	IOQ Protocol.
10.3	Warranty Letter for 1 year from the date of supply.
10.4	Operation and maintenance manuals shall be provided.

10.5	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of completion.
10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Thermo fisher,eppendorf, Rota
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-TCC 02	Hib	IPQC Room	BIG107	400X400	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Deep Freezer**

Document No.: DS-DPF 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Deep Freezer- Low Temperature (Vertical)				
F4	BCG	F4-DPF 02	250	1
W4	WARE HOUSE	W1-DPF 02,03,04	250	3 Sr 2
R1	MEASLES	R1-DPF 02	250	1
Deep Freezer- Low Temperature (Horizontal)				
B1	HiB	B1-DPF 02,03,04	460	3
Deep Freezer- Ultra Low Temperature				
Q1F	Mycoplasma Lab	Q1F-DPF 02	250	1
B1	Hep-B	B1-DPF 02	250	1
F4	BCG	F4-DPF 02	250	1
R1	MEASLES	R1-DPF 02-07	250	6
B1	HiB	B1-DPF 03	400	1
F1	VVF-MR	F1-DPF 02-03	250	2

NNE Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	25-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S. Shukla	25-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		25-05-2017

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: BCG-Bulk Jayarani	AM		05-06-2017
User department: Ware house	DM		05-06-2017
User department: MR Kuldip Mane	AM		05.06.2017
User department: MBB	DM		05.06.2017
User department: Quality Control	DM	TJ at Shukla for Dave	05.06.2017
User department: Viral Vaccine Formulation Rajendra Kumar	AM	S. Rajendra	05.06.2017
Project / Engineering department VISHNU.S	AM	S.	20.06.2017

nne		HBL HLL BIOTECH LIMITED	
Equipment Specification Data Sheet		**Equipment Name: Deep Freezer**	
Document No.: DS-DPF 02			**Revision: 00**
Project No.: 120310		**Project Name:** Integrated Vaccines Complex, Chengalpattu	
Approved by			
Head of the department Rabies Vaccine bulk Production MBB	NA	NA	NA
Head of the department Animal House BCCH	NA	NA	NA
Head of the department Quality Control			27-06-2017
Head of the department Viral Vaccine Formulation			27-06-2017
Head of the department (Quality Assurance)			27-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 02	
	Revision No.	00	

1	Process Requirements		
1.1	It is used to store material at low temperature		
2	**Equipment ID**	**Capacity (L)**	**Type**
2.1	F4-DPF 02	250	Vertical
2.2	W1-DPF 02-04	250	Vertical
2.3	R1-DPF 02	250	Vertical
2.4	B1-DPF 05-06-07	460	Horizontal

3	Technical Specification	
3.1	Model	cGMP compliant
3.2	Operating Temperature	-20°C
3.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.5	Shelves (W X D mm)	Removable shelves, no.of shelves vendor to specify based on capacity (minimum 3-5 nos to be provided) Shelves not applicable incase of horizontal deep freezer
3.6	Height between the shelves (mm)	Vendor to specify based on the above mentioned capacities.
3.7	Outer Door type	Single door
3.8	Compressor type	Hermetic compressor shall be provided
3.9	Refrigerant	CFC free (non flammable)
3.10	Temperature precision (setting resolution)	± 0.5 °C
3.11	Temperature resolution	± 0.1 °C
3.12	Temperature control range	-20 to -30 °C
3.13	Control & Display	Touch key pad with LED display mounted in the door or top of the door
3.14	Tempertaure Regulation	Microprocessor controlled
3.15	Temperature uniformity	± 2°C across the internal chamber
3.16	Validation Port	Ports for inserting probes for temperature mapping to be provided
3.17	Battery back up for panel	To be provided
3.18	Set point security	To be provided
3.19	Chart Recorder	To be provided
3.20	Air circulation	Positive Forced Air circulation
3.21	Total quantity	~~8 Nos~~ 7 Nos

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 02	
	Revision No.	00	

3.22	power requied (KW)	To be compatible to standard Indian power supply sockets	
4	**Material of Construction**		
4.1	Body Construction	Interior	SS 304
4.2		Shelves	Adjustable shelf, SS 304
4.3		Exterior	cGMP compliant
4.4		Inner Door	SS 304 door for each shelf (not applicable for horizontal deep freezer)
4.5		External Door	cGMP compliant
4.6	Gaskets, seals, o-rings	Gasket material - Silicon , Seals O- rings - Food grade Non toxic cGMP Material	
4.7	Insulation	Polyurethane Foam (PUF)	
4.8	All welds shall be ground finish		
5	**Specific Equipment requirement**		
5.1	The design of the equipment shall facilitate efficiency and easy cleaning		
5.2	Auto defrost to be provided		
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
5.4	Freezer shall be fitted with lockable caster wheels for easy transportation		
5.5	The control shall be microprocessor based with digital display cum controller.		
5.6	Key lock for Parameter change Protection to be provided		
5.7	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer.		
5.8	Interface port RS 232/ RS 485 to transfer data to be provided.		
5.9	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs.		
5.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.		
5.11	Audio Visual Alarms for parameters like high temperature, low temperature,door opening shall be provided.		
5.12	Door lock should be ergonamic,easy to clean and completely moulded		
5.13	Self closing door (Automatic) shall be provided.		
5.14	Temperature mapping during installation is required.		
5.15	Single compresser shall be provided.		
5.16	Temperature sensor PT 100 / Thermistor should be provided.		
5.17	Equipment shall be compatible for cleaning with all standard disinfectants.		
6	**Other requirement**		
6.1	Training / demonstration to be provided to users on operation and cleaning to be provided.		
7	**Regulatory guidelines / standards**		
7.1	CE certification		
8	**Safety requirements**		
	Following facilites must be provided to protect personnel and equipment:		

8.1	Emergency stop function on accessible area.
8.2	Noise level Should not be more than 60 decibels.
8.3	Proper earthing should be provided.
8.4	No sharp edges/Corners, crevices, in the equipment.
8.5	Approprite closure of all parts
9	**Documents**
	Following documents,but not limited to these, are expected from the vendor as part of supply package in hard copy as well as editable electronic file.
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
9.5	List of standard spare parts with ordering information.
10	**Timelines**
10.1	Not Applicable
11	**List of Preferred make**
11.1	Panasonic,JeioTech,Arctiko,Thermo scientific,Newtronics.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in	Room height in mm
F4-DPF 02	BCG	Seed	F4G028	4000X4000	2700
W1-DPF 02	WARE HOUSE	NA	NA	NA	NA
W1-DPF 03	WARE HOUSE	NA	NA	NA	NA
W1-DPF 04	WARE HOUSE	NA	NA	NA	NA
R1-DPF 02	MEASLES	Media Preparation	R1G042	5400X8095	2700
B1-DPF 02-04	HiB	Deep Freezer Room	B1G134	3501 x 3550	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure (specific equipment details)

Not Applicable.

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Deep Freezer- Ultra Low Temperature	
	Document No.	DS-DPF 02b	
	Revision No.	00	

1	Process Requirements	
1.1	It is used to store materials at Ultra low temperature.	
2	**Equipment ID**	**Capacity (L)**
2.1	Q1F-DPF 02	250
2.2	B1-DPF 02	250
2.3	F4-DPF 02	250
2.4	R1-DPF 02-07	250
2.5	B1-DPF 03	400
2.6	F1-DPF 02-03	250

3	Technical Specifications	
3.1	Model	cGMP compliant
3.2	Operating Temperature	– 80°C
3.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.5	Shelves (W X D mm)	Removable shelves, no.of shelves vendor to specify based on capacity (minimum 3-5 nos to be provided)
3.6	Height between the shelves (mm)	Vendor to specify based on the above mentioned capacities.
3.7	Outer Door type	Single door
3.8	Refrigerant	CFC free, R404A
3.9	Temperature precision (setting resolution)	± 0.3 °C
3.10	Temperature resolution	± 0.1 °C
3.11	Control & Display	Touch key pad with LED display flushed on the door
3.12	Temperature Regulation	Microprocessor controlled
3.13	Temperature uniformity	± 3°C
3.14	Validation Port	Ports for inserting probes for temperature mapping to be provided
3.15	Battery back up for panel	To be provided
3.16	Set point security	To be provided
3.17	Chart Recorder	To be provided
3.18	Air circulation	Natural Circulation
3.19	Total quantity	12 Nos.
3.20	power requirement	To be compatible to standard Indian power supply sockets

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Deep Freezer- Ultra Low Temperature	
	Document No.	DS-DPF 02b	
	Revision No.	00	

4	**Material of Construction**		
4.1	Body Construction	Interior	SS 304
4.2		Shelves	Adjustable shelf, SS 304
4.3		Exterior	cGMP compliant
4.4		Inner Door	SS 304 door for each shelf
4.5		External Door	cGMP compliant
4.6	Gaskets, seals, o-rings	Gasket - Silicon, seals, o-rings- Food Grade/ nontoxic material	
4.7	Insulation	CFC Free,Vaccum Insulation	
4.8	All welds shall be ground finish		
5	**Specific Equipment Requirements**		
5.1	The design of the equipment shall facilitate efficiency and easy cleaning		
5.2	Auto defrost to be provided		
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
5.4	Freezer shall be fitted with lockable caster wheels for easy transportation		
5.5	The control shall be microprocessor based with digital display cum controller.(SMS alert at the time of deviation temperature)		
5.6	Key lock for Parameter change Protection to be provided		
5.7	Temperature to be recorded, monitored and displayed.Temperature probe installed in freezer .		
5.8	Interface port RS 232 to transfer data to be provided .		
5.9	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
5.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.		
5.11	Audio Visual Alarms for parameters like high temperature, low temperature shall be provided.		
5.12	Door lock should be ergonomic,easy to clean and operate,moulded type		
5.13	Self closing door (Automatic) shall be provided.		
6	**Other Requirement**		
6.1	Training/Demo for the users on operating and cleaning to be provided.		
7	**Regulatory guidelines / Standards**		
7.1	CE certification.		
8	**Safety Requirements**		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Appropriate closure of all parts		
8.2	Emergency stop function on accessible area.		

8.3	Noise level Should not be more than 60 decibels.
8.4	Proper earthing should be provided.
8.5	No sharp edges/Corners, crevices, in the equipment.
9	**Documents**
	Following documents,but not limited to these, are expected from the vendor as part of supply package in hard copy as well as editable electronic file.
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
9.5	List of standard spare parts with ordering information.
10	**Timelines**
10.1	Not Applicable
11	**List of Preferred make**
11.1	Panasonic,JeioTech,Arctiko,Thermo scientific,Newtronics.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-DPF 02	Mycoplasma	Positive culture	Q1F018	19m2	2700
B1-DPF 02	Mbb-Hep B	Seed lab	BIG006	23m2	2700
F4-DPF 02	BCG	SEED	F4G028	6800X2550	2700
R1-DPF 02-04	R1G014	Deeep Freezer Room	R1G014	4450X5900	2700
R1-DPF 05-07	MR	Deeep Freezer Room	R1G021	4075X5900	2700
B1-DPF 03	MBB-Hib	Seed lab	BIG109	18m2	3000
F1-DPF 02-03	VVF -MR	Deep Freezer room	F1G052	6175X4075	3000

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	0	All	New Document

Table-3: Annexure (if any)

Not Applicable

nne | HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Hot Air Oven**

Document No.: DS-HAO 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity(L)	Quantity
R1	Measles	R1-HAO 02	500	1
F1	VVF-Measles	F1-HAO 02	500	1
W1	Ware House	W-HAO 02	200	1
Q1F	Mycoplasma	Q1F-HAO 02	500	1

NNE Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	26-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For [signature] T.S.Shibu	26-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish	[signature]	26-05-2017

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: MR Kuldip Mane	A.M	[signature]	06.06.2017
User department: VVF Kuldip Mane	AM	[signature]	06.06.2017
User department: Ware house SUJITH S.R	DM	[signature]	06-06-2017
User department: Quality Control [illegible]	DM	B. Anandhachandran	06.06.2017
Project / Engineering department VISHNU S	AM	S. [signature]	20.06.2017
Approved by			
Head of the department: MMR Dr. Kumaran	DVP	[signature]	21-06-2017
Head of the department: VVF Dr. Kumaran	DVP	[signature]	21-06-2017
Head of the department: Warehouse [illegible]	Head - Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department: Quality Control [illegible]	SM	[signature]	22-06-2017
Head of the department (QA) [illegible]	DVM	[illegible]	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Hot Air Oven	
	Document No.: DS-HAO 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	It is used for Dry Heat Sterilisation and Drying of Glasswares.	
2	**Equipment ID**	
2.1	R1-HAO 02	
2.2	F1-HAO 02	
2.3	Q1F-HAO 02	
3	**Technical Specification**	
3.1	Model	cGMP
3.2	Type	Table Top/Floor Mounted
3.3	Quantity	3 nos.
3.4	Temperature Range	Ambient +5 to 300 °C
3.5	Accuracy	± 2 °C
3.6	Control and Display	Timer Digital temperature setting with an accuracy of one degree, DS control with integrated timer 0 to 99.59 hrs.
3.7	Power Requirement	To be compatible with standard Indian power supply sockets.
4	**Material of Construction**	
4.1	Outer Body	SS 304/MS Epoxy powder coated reinforced by deep drawn ribbing with integrated and protected large area heating on four side exterior body alloy 304,rust - resistant and easy to clean.
4.2	Inner Body	Easy to clean interior,made of stainless steel SS316L.
4.3	Trays	SS 316L Perforated 3 or more adjustable.
5	**Specific Equipment Requirements**	
5.1	The gap between inner & outer walls of chamber should be fitted with high grade polyurathane foam (PUF), to ensure maximum thermal efficiency.	
5.2	Heating elements should be made of high grade chrome plated nicrome wire.	
5.3	Function set point/process delay function - process time should not start until the set temperature is reached.	
5.4	Ventilation forced air circulation by quite air turbine,adjustable in 10% increments, vent connection with restrictor flap.	
5.5	Sensors 2 PT 100 sensors Class A in 4 wire circuit,mutually monitoring the performance at the same temperature value.	
5.6	All the control switches & pilot lamps must be fitted on the front panel.	
5.7	Display resolution of display set point values 0.1 °C upto 99.9 °C, 0.5 °C from 100 °C and for actual values 0.1 °C (LED) solid state relays for low noise operation.Warm up timing to reach 150 °C in 40-50 min.	
5.8	Alarm Audio/Visual alarm for set temperature devation,door open and other parameter devation.	

5.9	Over Temperature protection additionally integrated over and under-temperature monitor,automatically following the set point valve at a preset tolerance range:alarm in case of over or under temperaure,heating is switched off in case of over temperature.
5.1	Three or more adjustable perforated stainless steel racks must be provided.
5.11	Control Adaptive multifunctional digital PID - Microprocessor controller with 2 high - definition TFT-colour display,self diagnostics for fault analysis parameters adjustable and control temperature(Celsius or Fahrenheit), fan speed, air flap position, programmable timer, time zones.
5.12	Appropriate floor clearance to be provided with adjustable caster wheels for floor mounted type equipment for easy cleaning.
5.13	Equipment shall be compatible for cleaning with all standard disinfectants.
5.14	Ventilation port and validation port must be provided.
6	**Other Requirement**
6.1	Training / Demo for the users on operation and cleaning to be provided.
7	**Regulatory Aspects**
7.1	The equipment shall be as per cGMP standards.Validation services with complete qualification packages.General compliance services,hardware and system suitablity.
7.2	CE certification.
8	**Safety Requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
8.3	CE certification,error detection and display with audio visual alarm system for output signal, voltage fluctuations, process, temperature devation.
9	**Documents**
	Following documents, but not limited to these, must be provided by the vendor as part of the supply package in hard copy as well as editable electronic file.
9.1	IOQ documents. & PQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site. PQ documents also required
9.3	Warranty letter for 1 year the date of supply.
9.4	List of standard spare parts with ordering information.
9.5	Calibration certificate of critical instruments with respect to traceable national reference standard instrument and their procedure.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Binder, Memmert, Thermo Scientific, Newtronics.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

Equipment Specification Data Sheet HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Hot Air Oven	
	Document No.: DS-HAO 02	
	Revision No.: 00	

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
R1-HAO 02	Measles	FumeHood + Hot air ovens	R1G040	4600X3995	2400
F1-HAO 02	VVF- Measles	Wash area (Testing)	G1G100	11400×5100	2700
W1 - HAO 02	Warehouse	NA	NA	NA	NA
Q1F-HAO 02	Mycoplasma Lab	Wash area	Q1F013	11400×5100	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Peristaltic pump**

Document No.: DS-PSP 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	Hep-B	B1-PSP 02-09	100 ml to 3000ml	8
B1	Hep-B	B1-PSP 10-14	1000 ml to 10000ml	5
F4	BCG	F4-PSP 02-03	100 ml to 3000ml	2
R1	Measles	R1-PSP 02-03	100 ml to 3000 ml	2
B1	HiB	B1-PSP 15-24	10 ml to 3000ml	10
F1	VVF-Measles	F1-PSP 02	100 ml to 3000ml	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		23-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	for T.S.Shukla	23-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		23-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB	DM		05-06-2017
User department: BCG Jayavani	AM		05-06-2017
User department: MR Kuldip Mane	AM		05-06-2017

Equipment Specification Data Sheet		**Equipment Name: Peristaltic pump**	
Document No.: DS-PSP 02			**Revision: 00**
Project No.: 120310		**Project Name:** Integrated Vaccines Complex, Chengalpattu	
Project / Engineering department VISHNU.S	A.M		21-06-2017
Approved by			
Head of the department Bacterial Formulation	DGM		05.06.2017
Head of the department Rabies Bulk	NA	NA	NA
Head of the department Quality Control Dr. SUPRIYA BABU	DQM	Dr. Suprya Babu	06-06-2017
Head of the department Viral Formulation Dr. R. LAKSHMAN	DVP		05-06-2017
Head of the department (QA) Dr. SUPRIYA BABU	DQM	Dr. Suprya Babu	06-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Peristaltic Pump	
	Document No.: DS-PSP 02	
	Revision No.: 00	

1	Process requirements		
1.1	The peristaltic pump will be used with sterile tubing for aseptic transfer of various process fluids such as buffers and cell culture media in a cGMP clean room facility.		
2	**Equipment ID**	**Flow rate**	**Quantity**
2.1	B1-PSP 02-09	100 ml to 3000ml	8 nos.
2.2	B1-PSP 10-14	1000 ml to 10000ml	5 nos.
2.3	F4-PSP 02-03	100 ml to 3000ml	2 nos.
2.4	R1-PSP 02-03	100 ml to 3000 ml	2 nos.
2.5	B1-PSP 15-24	10 ml to 3000ml	10 nos.
2.6	F1-PSP 02	100 ml to 3000ml	1 no.

3	Technical Specification	
3.1	Model	cGMP compliant
3.2	Type	Portable type, with variable speed
3.3	Display (RPM)	LED
3.4	Speed regulation (accuracy)	± 0.25 %
3.5	Dimension (L x W x H) in mm	Vendor to specify
3.6	Suction axis	Horizontal
3.7	Tube sizes (Internal/External)	Vendor to specify as per flow rate requirements
3.8	Operating temperature	5 °C–40 °C
3.9	Relative humidity	10–90 %
3.10	Displacement	Positive
3.11	Rotor Speed	0.1 - 600 rpm
3.12	Pump head	Single, should be compatible with silicon tubing of sizes 3.2 mm to 9.6 mm
3.13	Operation	Continuous and dosing
3.14	Pressure Range	20-40 psi
3.15	IP rating	IP 55/ IP 66
3.16	Motor direction	Clockwise and counter clock wise

3.17	Shipping Weight	Vendor to specify
3.18	Quantity	28 Nos
3.19	Power Requirement	To be compatible to standard Indian Power supply Socket
4	**Material of Construction**	
4.1	Main body	SS
4.2	Rollers, Pump case, Shaft, Bracket	SS
4.3	Tube	Platinum cured silicon tubing USP Class VI compliant
5	**Specific Equipment requirement**	
5.1	Individual peristaltic pump package should include (not limited) pump, pump head and 3 meters each of required sizes of platinum cured silicone tubing.	
5.2	The supplied pump head should accept multiple tubing sizes and operate to deliver the required minimum and maximum volumes.	
5.3	Peristaltic pump for continuous operation and pumping of process fluid along with metering the volume of fluid.	
5.4	Microprocessor controlled with soft-touch keypad and with easy-to-read LCD Screen along with LED light display to show the mode of the pump.	
5.5	Digital variable speed based pump drives; Stepper motor drive for uniform rpm digital variable speed.	
5.6	Digital speed setting, reversible flow, programmable pump.	
5.7	Pump speed should not vary with power fluctuations.	
5.8	Autocalibration shall be provided for the equipment with ID.	
5.9	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	**Other requirement**	
6.1	Should be certified as water tight.	
6.2	Manual/ analog/ digital RS 232 / 485 control required	
6.3	Training/Demo for the users on operation and cleaning to be provided.	
7	**Regulatory aspects**	
7.1	CE certification	
8	**Safety requirements**	
	Following facilites must be provided to protect personnel and equipment:	
8.1	Pump head should be covered with the safety enlcosure	

8.2	In event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices that the equipment and the product remain in a safe condition.
8.3	Noise level should be less than 85 db at 1 meter distance.
8.4	Appropriate closure of all parts.
8.5	Proper earthing is necessary.
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in the hard copy as well as editable electronic file
9.1	IOQ documents
9.2	Operation and maintenance manual should be provided along with IOQ docments during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibartion certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10	**Timelines**
10.1	Not applicable
11	**Preferred list of Makes**
11.1	Watson Marlow, Master Flex, ISMA tec, Lambda
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1 PSP 02-06	Hep-B	Fermentation Room	BIG007	2380 x 4910	2700
B1 PSP 07-09	Hep-B	Media Prepn	BIG019	6090 x 8940	2700
B1 PSP 10-11	Hep-B	Fermentation Room	BIG007	2380 x 4910	2700
B1 PSP 12	Hep-B	Continous Centrifuge	BIG010	2380 x 4910	2700
B1 PSP 13-14	Hep-B	Adsorption &Desorption room	BIG040	2380 x 4910	2700
F4 PSP 02	BCG	Harvest & Purification	F4G021	5200 x 6890	2700
F4 PSP 03	BCG	Media Prepn	F4G009	5200 x 6890	2700
R1 PSP 02	Measles	Cell culture - Measles	R1G071	3800X4500	2700

Equipment Specification Data Sheet HLL Biotech Limited, Chennai					
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED	
	Equipment Name	Peristaltic Pump			
	Document No.	DS-PSP 02			
	Revision No.	00			
R1 PSP 03	Measles	Cell culture - Rubella	R1G093	4830X3650	2700
B1 PSP 15-17	HiB	Polysaccharide purification	B1G136	6000 X 5000	2700
B1 PSP 18-20	HiB	Conjugation&Purification Room	B1G133	6000 X 5000	2700
B1 PSP 21-23	HiB	Media Prepn	B1G118	6000 X 5000	2700
B1 PSP 24	HiB	Buffer Staging	B1G124	9218 X 5801	2700
F1-PSP-02	VVF-Measles	Blending and Formulation	F1G080	9126 X 5750	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
11-07-2014	Niharika Ruhela	00	-	New document
9-09-2014	Niharika Ruhela	01	All	Updated as per comments received from HBL dated 13-05-2014
07-01-2015	Yogesha M J	02	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office
06-05-2015	Niharika Ruhela	03	All	Updated as per comments from client dated 27-02-2015

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Air Sampler**

Document No.: DS-ASA 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	Measles	R1-ASA 02-03	-	2
F4	BCG	F4-ASA 02-04	-	3
B1	MBB	B1-ASA 02-04	-	3
W1	WareHouse	W1-ASA 02-03	-	2
Q1F	Mycoplasma Lab	Q1F-ASA 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer	Sandeep	24-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for T.S. Shukla	24-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & finish		24-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Measels Kuldip Mane	AM		05-05-2017
User department: BCG Jayavani.K	AM		05-06-2017
User department: MBB M. RAJESH	DM		05-06-2017
User department: Warehouse SUJITH.S.R	DM		05-06-2017
User department: Quality Control V. CHANDRAMOHAN	DM		05-06-2017
Project / Engineering department VISHNU.J	AM		19.06.2017
Approved by			
Head of the department: Measles K.R. LAKSHMANAN	DVP		21-06-2017
Head of the department: BCG V. Manjula	Head - Bacterial Vaccines	M. V. Subrahmanyam	22-06-2017
Head of the department: MBB V. Manjula	Head Bacterial Vaccines	M. V. Subrahmanyam	22-06-2017
Head of the department: Warehouse V. Manjula	Head Bacterial Vaccines	M. V. Subrahmanyam	22-06-2017
Head of the department: Quality Control V. CHANDRAMOHAN	DM	for V. Raji	08-06-2017
Head of the department: QA	Asst Mgr		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name:	Air Sampler	
	Project #:	120310	
	Document #:	DS-ASA 02	

1	**Process requirements**	
1.1	This equipment is used for microbial monitoring of total suspended air borne particuates in clean rooms/sterile environments	
2	**Equipment ID**	
2.1	R1-ASA 01-02	
2.2	F4-ASA 01-03	
2.3	B1-ASA 01-03	
2.4	W1-ASA 01-02	
2.5	Q1F-ASA 01	
3	**Technical Specification**	
3.1	Model	cGMP with CE marking
3.2	Type	Portable
3.3	Accessories required	SS 316 aspirating head,Battery pack,Battery charger,integrated port for data transfer and carry case.
3.4	Quantity	11 nos
3.5	Noise level	50 dBA to 1 meter
3.6	Remote control	Interval sampling,delayed start can be followed by infrared remote control
3.7	Sampling program	50-9999 litres
3.8	Sample volume	1000 litres
3.9	Display	LCD display with alphanumerical keypad
3.10	Battery	Chargeable battery
3.11	Battery Life	5-8 hrs
3.12	Airflow	100-300 litres/minute
3.13	Sampling time	5-10 minutes
3.11	Weight	Not more than 3 kg
3.12	Charger	100-200 V charger
3.13	Connectors	Connectors are protected from corrosive gas or liquid with folding caps.
3.14	Dimensions	A per user requirement
3.15	Sampling grid	Stainless steel 316 L, Autoclavable
3.16	Software compliance	21 CFR Part 11 compliance
3.17	Keyboard	Digital Display
4	**Material of Construction**	
4.1	Outer Body	As per vendor specification.
5	**Specific Equipment requirment**	
5.1	Design avoids turbulence in unidirectional air flow and re-aspiration of tested air in accordance with ISO specifications.	
5.2	Real time with date and calibration reminder	
5.3	Should have integrated mass flow sensor	
5.4	Fully comply national and international standards for environmental monitoring	
5.5	Low running cost & opeational flexibility	
5.6	100% sampling efficiency	
5.7	The equipment shall be able to withstand the mechanical stresses.	
5.8	Customisable for different sample volumes	
5.9	The equipment should be provided with handle to carry from one place to other place easily.	
6	**Other requirement**	
6.1	The equipment should be easy to use and clean.	
6.2	All bolts,nuts on the exterior part of equipment should be with cap head or cap nut	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: Air Sampler	
	Project #: 120310	
	Document #: DS-ASA 02	

6.3	There should be no crevices,so as to avoid dust accumulation.
7	**Regulatory guidelines / standards**
7.1	The equipment shall be as per cGLP standards.
8	**Safety requirements**
8.1	Appropriate closure of all parts
8.2	On power failure equipment should come in failsafe condition
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:
9.1	IQ/OQ/PQ validation documentation/onsight activation
9.2	Operation and maintenance manuals
9.3	Calibration certificate should be provided
9.4	One year Warranty letter.
9.5	List of standard spare parts with ordering information.
9.5	Onsite calibration / other terms of calibration
9.6	Training for the technical persons to be included to handle the equipment.
10	**Preferred list of makes**
	Merck Millipore, AES(Biomerieux), SAS
11	**Timelines**
	Not Applicable
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
R1-ASA 01,02	Measles	NA	NA	NA	NA
F4-ASA 01,02,03	BCG	NA	NA	NA	NA
B1-ASA 01,02,03	MBB	NA	NA	NA	NA
W1-ASA 01,02	Ware House	NA	NA	NA	NA
Q1F-ASA 01	Mycoplasma Lab	NA	NA	NA	NA

Table 2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table 3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Apo Trinocular Stereo Microscope

Document No.: DS-ATSM 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1F	Mycoplasma	Q1F-ATSM-01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	24-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S.Shukla	24-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish	K	24-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control N. KRISHNAPRIYA	DM	N. Kpj	07-06-2017
Project / Engineering department VISHNU. J	AM	J. Vishnu	19-06-2017
Approved by			
Head of the department: Quality Control Sanjeev Kumar. R	SM	Sk	20-06-2017
Head of the department (QA)	DQM	D. Suresh Babu	21-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Apo Trinocular Stereo Microscope	
	Document No.	DS-ATSM 01	
	Revision No.	00	

1	**Process requirements**	
1.1	It is used for observing hemocytometer, 96 well plate, Lab-Tek chambers and Petridishes	
2	**Equipment ID**	
2.1	Q1F-ATSM- 01	
3	**Technical Specification**	
3.1	Model	NA
3.2	Type	Stereo (Trinocular)
3.3	Optical Type	Parallel-optics type or Common Objective system
3.4	Objective	Plan Apo 1X (WD 70 mm or better)
3.5	Zoom ratio	10:1
3.6	Zoom Range	1-8 X or better
3.7	Working distance	Working Distance 52 mm to 70 mm or better
3.8	Total Magnification	80 X times with plan Apo
3.9	Eye piece	10 X FOV 22 mm
3.10	Interpupillary distance adjustment	52 - 70 mm or Better
3.11	Nose Piece	Double nose piece
3.12	Observation tube	Tiling Trinocular tube (100:0/0:100) with 0 to 30 degree inclination
3.13	Focusing Assembly	Coarse & Fine focusing
3.14	Stand	Transmited light source with compact slim base for colourless sample and transparent sample observation
3.15	Light Source	LED
3.16	Illumination mode	Both transmitted LED and Episcopic Fibre double arm illuminator
3.17	Stage height (From desk)	40 mm or better
3.18	Epiflourescent Attachment	Flouresent attachment with four filter assembly with provision for uniform illumination through the special lens
3.19	Epiflourescent Light source	Mercury presented fibre illuminator 120W/130W for 2000 hours or Better light source
3.20	Camera Type	5 mega pixel CCD camera or better
3.21	Camera spec	Vendor to specify
3.22	Quantity	1 No
3.23	Power required	To be compatible with standard Indian power supply sockets.
4	**Material of Construction**	
4.1	Body	Ergonomic body with stain and particle resistant finish.
5	**Specific Equipment Requirements**	
5.1	Binocular head should rotate 360° and inclined at 30° to 45°. Features interpupillary and dioptric adjustment.	
5.2	Minimum magnification of the microscope should be 10X replace by 4X.	
5.3	All external parts of the microscope should be disinfectable.	

5.4	Nose piece position should be, reversed, knurled grip for easy operation. Should feature smooth operation and with positive click stops.
5.5	Stage should be delivering a high level of fluid motion control and longevity. Motion must be controlled with a right-hand low-position coaxial control and it should be driven by a rack and pinion system.
5.6	The microscope should have two focusing knobs mounted together.The large knob should be for coarse focus adjustment.The smaller knob should be for fine focus adjustment.
5.7	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.
5.8	Provision for Camera attachment should be provided.
5.9	Provision for epi fluorscence attachment should be provided.
5.10	Equipment shall be compatible for cleaning with all standard disinfectants.
6	**Other Requirements**
6.1	The instrument must be portable.
6.2	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover the equipment when not in use.
6.3	Cleaning cloth / paper should be provided to clean optical surfaces.
6.4	Accessories to be provided :Spare Fuses, Spare lamps,Draw tube, spare objectives, sub-stage white LED Lamp if used
6.5	Training /Demo for users on operation and cleaning to be provided.
7	**Regulatory aspects**
7.1	CE certification
8	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Leica, Zeiss, Nikon, Olympus
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: Apo Trinocular Stereo Microscope	
	Document No.: DS-ATSM 01	
	Revision No.: 00	

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-ATSM 01	Mycoplasma	Instrument Lab	Q1F009	16m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Chiller Water Bath**

Document No.: DS-CWB 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB (Hib)	B1-CWB 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer	Sandeep	30-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	For T.S.Shukla	30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		30-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB ANOOP Kumar	AM		07-06-2017
Project / Engineering department VISHNU. S	AM		16-06-2017
Approved by			
Head of the department: MBB M.V.Subramanyam V. Mamtha	Head-Bacterial Vaccines	M.V. Subramanyam	22-06-2017
Head of the department (QA)	Dept		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Chiller Water Bath	
	Project #	120310	
	Document #	DS-CWB 01	

1	**Process requirements**	
1.1	A circulatory chiller water bath is a laboratory instrument used to incubate the sample at a constant temperature (low temperature) over a long period of time.	
2	**Equipment ID**	
2.1	B1-CWB 01	
3	**Technical Specification**	
3.1	Model	cGMP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply
3.3	Display	High resolution LCD display
3.4	Keypad	Touch-sensitive LCD panel with GUI icons
3.5	Tempaerature range	-10 °C to 100 °C
3.6	Operator temperature range	5 ± 3 °C
3.7	Temperature Resolution	0.1 °C
3.8	Temp. Control Accuracy	± 1°C of set temperature
3.9	Bath Cover	Lift-up bath cover
3.10	Refrigeration	CFC/HCFC free (cGMP compliant) and having circulating features
3.11	Reservior volume	Minimum 15 Ltrs.
3.12	Refrigeration	CFC/HCFC free (cGMP compliant)
3.13	Pump rate	Max 10Ltrs/Min & Pump rate should be adjustble
3.14	Alarm	Audible and visible alarm should indicate whenever there is a deviation from the set parameter
3.15	Drain valve	Yes
3.16	Programmability	Minimum 5 programme and should have power failure restart mode
3.17	PC Communication & Data management	PC controllable & USB port (For tranfer of operating data/history)
3.18	Electrical Supply	100 to 240 V, 50 to 60 Hz
3.19	Dimension, (W X D X H)	Vendor to specify
3.20	Weight	Vendor to specify
3.21	Quantity	1 No.
3.22	**Additional Requirements**	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
		Equipment Name: Chiller Water Bath	
		Project #: 120310	
		Document #: DS-CWB 01	
3.23	Temperature	a) In built temperature sensors for monitoring the cooling tempaeratures. b) Automatic temperaturecooling as per required for the process recipe. c) Temperature regulators shall be provided to increase or decrease cooling rates. d) In built thermometer shall be provided for on site temperature calibration.	
3.24	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. b) Menu and settings with customizable security levels using password should be provided. c) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. d) Touch key pads shall be provided for ease operation. e) User selectable operating modes shall be provided (automatic and mannual) g) External Pt100 sensor.	
4	**Material of Construction**		
4.1	Body frame	cGMP Compliance	
5	**Specific Equipment requirment**		
5.1	Appropriate failure detection and alarm notification.		
5.2	Chamber shall be insulated properly to maintain inner environment.		
5.3	Proper earthing is necessary.		
5.4	Appropriate closure of all parts.		
5.5	User calibration should be available.		
5.6	Equipment should be easily movable (caster & wheel lock sysstem)		
6	**Other requirement**		
6.1	Cleaning shall be done manually.		
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.		
6.3	Vendor to give code numbers for each component.		
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.		
7	**Accessories Required**		
7.1	Circulation fitting material (Tubing/Adapter/valves/connector).		
7.2	Additional tools for maintenance and repair.		
8	**Regulatory Aspects**		
8.1	cGMP compliances.		
8.2	CE certification.		

9	**Safety requirements**
9.1	Always follow appropriate laboratory practices when using this equipment.
9.2	Appropriate closure of all parts.
9.3	On power failure equipment should come in safe condition.
9.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
10.2	IOQ documents
10.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site
10.4	Warranty Letter for Minimum 1 year from the date of supply.
10.5	Vendor should provide list of standard spare parts with ordering information.
10.6	NPL traceable calibration certificates and calibration procedures
10.7	Vendor should provide list of change parts (if applicable) with ordering information
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Mettler Toledo, Thermofischer Scientific,Hach,HANNA
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-CWB 01	MBB (Hib)	Conjugation & Purification Room	BIG 133	43000 mm^2	NA

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Conductivity Meter**

Document No.: DS-CDM 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	Maesles	R1-CDM 02-03	-	2
B1	HiB	B1-CDM 02-04	-	3
F1	VVF-Measles	F1-CDM 02-03	-	2

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer	Sandeep	23-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	For. T.S. Shetty	23-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		23-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Measles Kuldip Mane	AM		05-06-2017
User department: MBB Anoop Kumar	A.M.		05-06-2017
User department: VVF Kuldip Mane	AM		05-06-2017
Project / Engineering department VISHNU.J	A.M		21-06-2017
Approved by			
Head of the department: Measles Dr. R. Lwmahow	DVP		22-06-2017
Head of the department: MBB Dr. Subramanyam V. Mantha	Head-Bacterial Vaccine	M.V. Subramanyam	22-06-2017
Head of the department: VVF Dr. R. Lwmahow	DVP		22-06-2017
Head of the department (QA) R. Suresh Babu	DGM	R. Suresh Babu	22-06-2017
Authorized by			
Project Authority	AM		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Conductivity Meter	
	Project #	120310	
	Document #	DS-CDM 02	

1	**Process requirements**	
1.1	The conductivity meter is intended to measure the conductivity of the liquid sample. The conductivity meter shall have additional features to measure the resisitivity and TDS.	
2	**Equipment ID**	
2.1	R1- CDM 02-03	
2.2.	B1-CDM 02-04	
2.3	F1-CDM 02-03	
3	**Technical Specification**	
3.1	Model	cGLP Model
3.2	Type	Digital, benchtop type
3.3	Conductivity range	0.001 µS/cm to 1000 mS/cm
3.4	Conductivity Resolution	Vendor to Specify
3.5	Conductivity Accuracy	± 0.5 %
3.6	Conductivity sensors	Vendor to Specify
3.7	Resisitivity Range	up to 100 meg ohm
3.8	Resolution	Vendor to Specify
3.9	Accuracy	± 0.5 %
3.10	TDS Range	400 g/l or better
3.11	TDS Resolution	Vendor to Specify
3.12	TDS Accuracy	± 0.5 %
3.13	Temperature range	Vendor to Specify
3.14	Temperature accuracy	± 0.1 ^{0}C
3.15	Display type	LCD/TFT
3.16	Memory	Storage of upto 300 measurement with date and time
3.17	Power supply	To be compatible to standard Indian power supply sockets
3.18	Quantity	7 Nos
3.19	Expected operational hours per day	24 hrs with stand-by mode

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Conductivity Meter	
	Project #	120310	
	Document #	DS-CDM 02	

4	**Material of Construction**	
4.1	Glass Electrode	The glass electrode must be made from Borosilicate glass for conductivity probe.
4.2	Body of the meter	Powder coated or Vendor to specify
5	**Specific Equipment requirment**	
5.1	Standard calibration buffer solutions to be provided - Two set, along with ordering information	
5.2	Reminder for Calibration	
5.3	LCD display to show the readings, Time,date and calibration points. And audible beep indications during valid key operation	
5.4	The Conductivity meter must have, stand with flexible arm, Electrode holder and universal power adaptor. Different cell constant probes to cover the range should be provided.	
5.5	One set of additional/ spare conductivity probe to be provided.	
5.6	The equipment shall be compatible for cleaning with all standard disinfectants.	
5.7	Equipment shall facilitate easy cleaning and maintanance with standard disinfectant	
6	**Other requirement**	
6.1	Training and demo for user on operation and cleaning to be provided	
7	**Regulatory aspects**	
7.1	CE certification	
8	**Safety requirements**	
8.1	Proper earthing is necessary	
8.2	Appropriate closure of all parts.	
9	**Documents**	
9.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**	
9.2	IOQ documents	
9.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site	
9.4	Warranty Letter for Minimum 1 year from the date of supply.	
9.5	Vendor should provide list of standard spare parts with ordering information.	
9.6	NPL traceable calibration certificates and calibration procedures	
9.7	Vendor should provide list of change parts (if applicable) with ordering information	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Conductivity Meter	
	Project #: 120310	
	Document #: DS-CDM 02	

10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Mettler Toledo, Thermofischer Scientific.Hach,HANNA
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
R1-CDM 01	Measles	R1G042	Media Prepn	5400X8095	2700
R1-CDM 02	Measles	R1G024	Washing Area	12203X5000	2700
B1-CDM-01	HiB	B1G118	Media Prepn	38 m2	2700
B1-CDM-02	HiB	B1G133	Conjugation	43m2	2700
B1-CDM-03	HiB	B1G106	Purification	128m2	2700
F1-CDM-01-02	VVF-MR	F1G049	Washing Area	6350X6275	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Cooling Batch Centrifuge**

Document No.: DS-CBC 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	MR Bulk	R1-CBC 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer		31-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	For T.S. Shukla	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MR Kuldip Mane	AM		12-06-2017
Project / Engineering department YISHNU. S	AM		21-06-2017
Approved by			
Head of the department: MR R.R. KUMARAN	DVP		23-06-2017
Head of the department (QA)	DGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name:	Cooling Batch Centrifuge	
	Project #:	120310	
	Document #:	DS-CBC 01	

1	**Process requirements**	
1.1	The cooling centrifuge can be used to determine the wet mass of the fermentation culture for IPQC testing purpose.	
2	**Equipment ID**	
2.1	R1-CBC 01	
3	**Technical Specification**	
	Centrifuge	
3.1	Model	cGMP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.4	Display	High resolution LCD display
3.5	Keypad	Touch-sensitive LCD panel with GUI icons
3.6	Speed range	Min 100 rpm to Max 15,000 rpm
3.7	Safety Functions	Automatic lid lock, Interlock Door, Dual Over Speed Detection, Non-contact Imbalance Detection and correction (15 gm tolerance), Abnormal Temp. Detection etc.
3.8	Programmability	Minimum 5 programme
3.9	Accel/Decel Profiles	Max. time 1 to 5 min from 0 to 1000 rpm/ Max. time 1 to 5 min. from 1000 to 0 rpm
3.10	Noise	< 62 db (at max rpm 15,000)
3.11	Maximum Capacity	>6 L capacity
3.12	Speed control accuracy	± 10 rpm
3.13	Temp. Control Accuracy	± 1°C of set temperature
3.11	Tempaerature range	0 °C to 40 °C
3.12	Temperature Resolution	0.1 °C
3.13	Data Communication	USB port (For tranfer of operating data/history.)
3.14	Operating Log Management	LAN :Factory Option PC and optional Log Manager Supporting cGMP
3.15	Alarm	Audible and visible alarm should indicate whenever there is a deviation from the set parameter
3.16	Refrigeration	CFC/HCFC free (cGMP compliant) and pre-chamber cooling facility
3.17	Electrical Supply & Voltage Stabilizer	100 to 240 V, 50 to 60 Hz
3.18	Dimension, (W X D X H)	Vendor to specify
3.19	Weight	Vendor to specify
3.20	Maximum RCF's	10,000 X g
	Rotor	
3.20	Type	Fixed angle, swing bucket and autoclavable (No decoloration)
3.21	MOC	Metal (Aluminium) (cGMP compliance)
3.22	Rotor chamber	Corrosion resistant Stainless Steel 316 Grade
3.23	Rotor lid	Metal (Aluminium) (cGMP compliance)
3.24	Rotor Identification	Automatic Rotor Identification and Rotor Cover Detector
3.25	Quantity	2 Nos. additional Rotor and PP autoclavable bottel and accessories along with each centrifuge.
3.26	Rotor Capacity	4 or 6 positions for 1500 ml or 1000 mL with lid including rotor lid.
	Additional Requirements	

3.26	Temperature	a) In built temperature sensors for monitoring the tempaerature. b) In built thermometer shall be provided for on site temperature calibration.
3.27	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. b) Menu and settings with customizable security levels using password should be provided. c) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. d) Touch key pads shall be provided for ease operation. e) User selectable operating modes shall be provided (automatic and mannual) f) Micro processer based controls for smooth operations
4	**Material of Construction**	
4.1	Body frame	cGMP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification.	
5.2	Chamber shall be insulated properly to maintain inner environment.	
5.3	Proper earthing is necessary.	
5.4	Appropriate closure of all parts	
5.5	Hinged type top cover should be provided, that can be operated using single hand	
5.6	Cooling mechanism should be provided to maintain the uniform temperature throughout the Operation.	
5.7	Low access height for easy loading and unloading of samples should be provided.	
5.8	Equipment should be easily movable (caster & wheel lock sysstem)	
5.9	After power failure it should be able to resume the same variables i.e., RPM, TIME and Temperature.	
6	**Other requirement**	
6.1	Cleaning shall be done manually.	
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.	
6.3	Vendor to give code numbers for each component.	
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
7	**Accessories required**	
7.1	Should be supplied with two additional rotor for each model	
7.2	Should be supplied with additional 2 set autoclavable centrifuge bottles with cap, Spatula.	
7.3	Additional tools for maintenance and repair.	
8	**Regulatory aspects**	
8.1	cGMP compliances.	
8.2	CE certification	
9	**Safety requirements**	
9.1	Always follow appropriate laboratory practices when using this equipment.	
9.2	Appropriate closure of all parts.	
9.3	On power failure equipment should come in fail safe condition.	
9.4	Noise level should not be more than 62 decibels at the distance of 1m from the equipment.	
10	**Documents**	
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**	

10.2	IOQ Protocol.
10.3	Warranty Letter of 1 year for centrifuge, Compressor and rotor 5 Years warranty from the date supply.
10.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site.
10.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of supply.
10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information.
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Thermo Fisher Scientific, Beckman, Hitachi, Sartorius.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

TABLE NO:1

Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
R1- CBC 01	MR Bulk	Cell Culture Room-2	R1G072	3800 X 4500	-

Table-2: Change Log

Date	Name	Revision	Section	Change Comment
16-01-2017	Sandeep Kumar	00	-	New document.

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Floor Mounted Cooling Batch Centrifuge

Document No.: DS-FMCC 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB,HiB Bulk	B1-FMCC 01-03	6L	3

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer	Sandeep	30-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for T.S. Shukla	30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & finish		30-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		06-06-2017
Project / Engineering department VISHNU. J	AM		19.06.2017
Approved by			
Head of the department: MBB M. Manikandan M. Mantha	Head-Bacterial Vaccines	M. V. Subrahmanyam	22-06-2017
Head of the department (QA)	QAM		03-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Floor Mounted Cooling Batch Centrifuge	
	Project #	120310	
	Document #	DS-FMCC 01	

1	**Process requirements**	
1.1	A cooling batch centrifuge is a laboratory instrument used for the separation and purification of temperature sensitive samples, based on density/mass.	
2	**Equipment ID**	
2.1	B1-FMCC 01-03	
3	**Technical Specification**	
	Centrifuge	
3.1	Model	cGMP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Display	High resolution LCD display
3.4	Keypad	Touch-sensitive LCD panel with GUI Icons
3.5	Speed range	Min 10,000 rpm to Max 15,000 rpm
3.6	Safety Functions	Automatic lid lock, Interlock Door, Dual Over Speed Detection, Non-contact Imbalance Detection (15 gm tolerance), Abnormal Temp. Detection etc.
3.7	Programmability	Minimum 5 programme
3.8	Accel/Decel Profiles	Max. time 1 to 5 min from 0 to 1000 rpm/ Max. time 1 to 5 min. from 1000 to 0 rpm
3.9	Noise	< 62 dBA (at max rpm 15,000)
3.10	Maximum Capacity	>6 L capacity
3.11	Speed control accuracy	± 20 rpm
3.12	Temp. Control Accuracy	± 1°C of set temperature
3.13	Tempaerature range	0 °C to 40 °C
3.14	Temperature Resolution	0.1 °C
3.15	Data Communication	USB port (For tranfer of operating data/history.)
3.16	Operating Log Management	LAN :Factory Option PC and optional Log Manager Supporting cGMP
3.17	Alarm	Audible and visible alarm should indicate whenever there is a deviation from the set parameter
3.18	Refrigeration	CFC/HCFC free (cGMP compliant) and pre-chamber cooling facility
3.19	Electrical Supply & Voltage Stabilzer	100 to 240 V, 50 to 60 Hz
3.20	Dimension, (W X D X H)	Vendor to specify
3.21	Weight	Vendor to specify
	Rotor	
3.22	Type	Fixed angle and autoclavable (No decoluration)
3.23	MOC	Metal (Aluminium) (cGMP compliance)
3.24	Rotor chamber	Corrosion resistant Stainless Steel 316 Grade

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Floor Mounted Cooling Batch Centrifuge	
	Project #	120310	
	Document #	DS-FMCC 01	

3.25	Rotor lid	Metal (Aluminium) (cGMP compliance)
3.26	Rotor Identification	Automatic Rotor Identification and Rotor Cover Detector
3.27	Quantity	2 Nos. additional Rotor and PP autoclavable bottel and accessories along with each centrifuge
3.28	**Additonal Requirements**	
3.29	Temperature	a) In built temperature sensors for monitoring the tempaerature. b) In built thermometer shall be provided for on site temperature calibration.
3.30	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. b) Menu and settings with customizable security levels using password should be provided. c) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. d) Touch key pads shall be provided for ease operation. e) User selectable operating modes shall be provided (automatic and mannual)
4	**Material of Construction**	
4.1	Body frame	cGMP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification.	
5.2	Chamber shall be insulated properly to maintain inner environment.	
5.3	Proper earthing is necessary.	
5.4	Appropriate closure of all parts	
5.5	Equipment should be easily movable (caster & wheel lock sysstem)	
6	**Other requirement**	
6.1	Cleaning shall be done manually.	
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.	
6.3	Vendor to give code numbers for each component.	
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
7	**Accessories required**	
7.1	Should be supplied with two additional rotor	
7.2	Should be supplied with additional 2 set autoclavable centrifuge bottles with cap, Spatula.	
7.3	Additional tools for maintenance and repair.	
8	**Regulatory aspects**	
8.1	cGMP compliances.	
8.2	CE certification	
9	**Safety requirements**	
9.1	Always follow appropriate laboratory practices when using this equipment.	
9.2	Appropriate closure of all parts.	

9.3	On power failure equipment should come in fail safe condition.
9.4	Noise level should not be more than 62 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
10.2	IOQ Protocol.
10.3	Warranty Letter for 1 year from the date of supply for centrifuge; Compressor and rotor 5 Years warranty
10.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site.
10.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of completion.
10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information.
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Thermo Fisher Scientific, Beckman, Hitachi, Sartorius.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm^2 (Area)	Room height in mm
B1-FMCC 01-03	MBB (Hib)	Polysaccharide purification room	BIG136	58000 mm^2	NA

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment	

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Egg Incubator**

Document No.: DS-EIC 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	MR	R1-EIC 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	31-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process	Tushar	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MR Kuldip mane	AM		12-06-2017
Project / Engineering department VISHNU. S	AM	S.	21-06-2017
Approved by			
Head of the department MR Dr. R. KUMARAN	DVP		22-06-2017
Head of the department (QA)	QAM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Egg Incubator	
	Document No.	DS-EIC 01	
	Revision No.	00	

1	**Process requirements**	
1.1	The egg incubator shall be used for incubation of SPF eggs under controlled conditions.	
1.2	The capacity of eggs should be minimum 1000 eggs.	
2	**Equipment ID**	
2.1	R1-EIC 01	
3	**Technical Specification**	
3.1	Model	cGMP Egg Incubator
3.2	Type	SS Double wall chamber provided with light inside, Single door on front side with locking arrangement and interlock with three point door micro switch and equipped with the exhaust damper on top of the chamber.
3.3	Capacity	1000 eggs
3.4	Utility (Compressed air/gas)	Minimum ½" pipe Operating Pressure: 4-6 kg
3.5	Temperature range	ambient+ 5 to 75°C
3.6	Temperature Stability	±0.2°C
3.7	Temperature Readability	0.1°C
3.8	Temperature Uniformity	± 0.6 °C @37 °C
3.9	View Glass	minimum 100 mm Dia
3.10	Temperature Controller	Microprocessor based
3.11	Display Unit	LED/LCD
3.12	Humidity Control	55 to 90 %.Rh
3.13	Interlocking	Electromagnetic door interlocking- Door Interlock with Chamber Fan, Over shoot Temperature Interlock, Low water interlock
3.14	Dimension (Chamber size,external size)	As per the volume specified above
3.15	Quantity	1 No's
3.16	Power Requirement	To be compatible to standard Indian power supply sockets
3.17	**Additonal Requirements:**	
3.18	Training/Demo for the users on the operation and cleaning to be provided.	
3.19	Equipment should poses universal safety requirment.	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Egg Incubator	
	Document No.	DS-EIC 01	
	Revision No.	00	

4	**Material of Construction**	
4.1	Contact part	S.S. 316
4.2	Non-contact part	S.S. 304
4.3	Structure	S.S.316L x 1mm thk. Insulated Double walled chamber.
4.4	Oscillation	Pneumatically operated, 45° angle, hourly left, right automatically during Incubation cycle.
4.5	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints c) All bolts, nuts on the exterior part of the equipment will be with cap head or cap nut
4.6	SS Tank	mimimum 5 Ltrs. SS Water Tank with water heater to control humidity.
4.7	Motor Blower, Air Heater	500 watt 4 no. of heaters
4.8	Alarm	Temp. High & Low Humidity High & Low Fan Fail Dry Wick Turn Fail
4.9	Gaskets, seals, O-ring	Food Grade/ nontoxic material;
4.10	Validation	Validation port to be provided to insert probes for temperature mapping
4.11	All welds shall be ground finish	
5	**Specific Equipment requirment**	
5.1	Microprocessor controller unit with humidity controller system.	
6	**Regulatory aspects**	
6.1	cGLP compliances.	
6.2	CE Certification	
7	**Safety requirements**	
7.1	Always follow appropriate laboratory practices when using this equipment.	
7.2	Appropriate closure of all parts.	
7.3	On power failure equipment should come in fail safe condition	
7.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Egg Incubator	
	Document No.: DS-EIC 01	
	Revision No.: 00	

8	**Documents**
	Following documents, but not limited to these,are expected from the vendor as part of the supply package in the hard copy as well as electronic file.
8.1	IOQ Protocol.
8.2	Warranty Letter for 1 year from the date of supply.
8.3	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
8.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.5	All equipment warranty should be valid for one year from the date of completion.
8.6	Vendor should provide list of standard spare parts with ordering information.
8.7	Vendor should provide list of change parts (if applicable) with ordering information
9	**Timelines**
9.1	Not Applicable
10	**Preferred list of Makes**
10.1	Esco,Thermo scientific,Binder,Memmert,Eppendorf.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
R1-EIC 01	MR	Incubator	R1G045	2350X3950	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
30-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne pharmaplan®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Refrigerator(GMP)**

Document No.: DS-RFR 02

Revision: 00

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Q1F	Mycoplasma	Q1F-RFR 01	300	1
R1	Measles	R1-RFR 01	300	1
F4	BCG	F4-RFR 01,02	800-1100	3
B1	MBB-HiB	B1-RFR 01,02,03	300	3

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	30-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process		30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		30-05-2017

nne pharmaplan®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Refrigerator(GMP)**

Document No.: DS-RFR 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Measles RAJENDRA. SIRAM	AM.	S.Rajendran	07-06-2017
User department: MBB - Hib Anoop	AM	Anoop	07-06-2017
User department: BCG Elayarani	AM	Elay	07-06-2017
User department: Quality Control P.A Sneka Chowdari	DM	P.A.Sneka Chowdari	07-06-2017
Project / Engineering department	DM		07-06-2017.
Approved by			
Head of the department Measles R. KUMARAN	DVP		22.06.2017
Head of the department MBB - Hib V. MANTHA	Head-Bacterial Vaccines	M.V. Subrahmanyam	23-06-2017
Head of the department BCG V. MANTHA	Head-Bacterial Vaccines	M.V. Subrahmanyam	23-06-2017
Head of the department Quality Control	DGM		23-06-2017
Head of the department (QA)	DGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED
		Equipment Name	Refrigerator (GMP)		
		Document No.	DS-RFR 02		
		Revision No.	00		
1	Equipment ID	Minimum Capacity (L) near to standard	Type/Model	Quantity (Nos)	Process Requirements
1.1	Q1F-RFR 01	300	GMP	1	It is used to store materials at 2-8 ºC
1.2	R1-RFR 01	300	GMP	1	
1.3	F4-RFR 01,02,03	800-1100	GMP	3	
1.4	B1-RFR 02-04	300	GMP	3	

2	Technical Specification		
2.1	Model	cGMP	
2.2	External dimension (W X D X H mm)	vendor to specify (based on the above mentioned capacity)	
2.3	Internal dimension (W X D X H mm)	vendor to specify (As per the capacity)	
2.4	Shelves (W X D mm)	vendor to specify (As per the capacity)	
2.5	Height between the shelves (mm)	vendor to specify	
2.6	No. of Shelves	vendor to specify (SS 304 Perforated shelves shall be adjustable)	
2.7	Temperature Range	2 °C to 8 °C	
2.8	Refrigerant	R 134a	
2.9	Temperature precision	± 0.5 °C	
2.10	Temperature stability	± 1 °C	
2.11	Temperature Resolution	± 1 °C	
2.12	Temperature uniformity	± 2 °C	
2.13	Air circulation	Forced air circulation	
2.14	Quantity	5 no.	
2.15	Power requirement	To be compatible to standard Indian Power supply socket.	
3	Material of Construction		
3.1	Body Construction	Interior	SS 304
3.2		Shelves	Adjustable,Perforated, SS304
3.3		Exterior	cGMP compliant exterior
3.4	Gaskets, seals, o-rings	Food Grade/ nontoxic material	
3.5	Insulation	Polyurethane foam(PUF)	

3.6	Door	Stainless steel door
3.7	All welds shall be ground finish	
4	**Specific Equipment Requirements**	
4.1	The design of the equipment should facilitate efficient and easy cleaning	
4.2	The equipment shall be compatible for cleaning with all standards disinfectants	
4.3	Refrigerator shall be fitted with lockable caster wheels for easy transportation.	
4.4	The control shall be microprocessor based with digital display cum controller.	
4.5	Key lock for Parameter change Protection to be provided.	
4.6	Temperature to be recorded, monitored and displayed. Chart recorder to be provided.(PT 100)	
4.7	Interface port RS 232 to transfer data to be provided.	
4.8	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery	
4.9	Audio visual alarms for parameters like high temperature, low temperature shall be provided and if door is open for > 5min	
4.10	Light on provision during door opening	
4.11	Door lock should be provided.	
4.12	Spring loaded, self closing door with 90º angle stay open feature should be provided with holder.	
4.13	Validation Ports to be provided for inserting probes for temperature mapping.	
4.14	Temperature mapping during installation is required.	
4.15	Single compressor should be provided.	
4.16	Equipment shall be compatible for cleaning with all standard disinfectant.	
4.17	Design Basis: Refer Annexure 1 for specific design of B4-RFR 06	
6	**Other requirements**	
6.1	Training/Demo for the users on operation and cleaning to be provided	
6	**Regulatory Aspects**	
6.1	CE certification.	
7	**Safety Requirements**	
	Following facilities must be provided to protect personnel and equipment:	
7.1	Proper earthing is necessary	
7.2	No sharp edges/Corners in the equipment.	
7.3	Appropriate closure of all parts.	
8	**Documents**	
	Following documents,but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.	
8.1	IOQ documents.	
8.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.	

8.3	Warranty letter for 1 year from the installation.
8.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
8.5	List of standard spare parts with ordering information
9	**Timelines**
9.1	Not Applicable
10	**List of Preferred makes**
10.1	Thermo scientific, Panasonic, JeioTech, Arctiko, Newtronics.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-RFR 01	Mycoplasma	Media Prepn	Q1F017	23m2	2700
R1-RFR 01	Measles	Media Prepn	R1G042	5400X8095	2700
B1-RFR 01	MBB-HiB	seed lab	B1G109	18m2	2700
B1-RFR 02	MBB-HiB	IPQC	B1G135	9m2	2700
B1-RFR 03	MBB-HiB	IPQC	B1G107	8m2	2700
F4-RFR-01	BCG	Media Storage	F4G041	39.3m2	2400
F4-RFR-02,03	BCG	Incubator Room	F4G029	8.8m2	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
17-01-2017	Sandeep Kumar	00	-	New document

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Gas Chromatography**

Document No.: DS-GCS 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-GCS 01	-	1
B1	Hep-B	B1-GCS 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	29-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process	Shende	29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		29-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control B. Abhijith Chowdari	DM	B. Abhijith Chowdari	07.06.2017
User department: MBB CH. RAJESH	DM		07-06-2017
Project / Engineering department VISHNU. J	AM	J.	20-06-2017
Approved by			
Head of the department Quality Control Sanjeev Kumar. R	SM		22-06-2017
Head of the department MBB V. Mantra	Head-Bacterial Vaccines	M. V. Subrahmanyam	22-06-2017
Head of the department (QA)	DGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Gas Chromatography	
	Document No.	DS-GCS 01	
	Revision No.	00	

1	**Process requirements**	
1.1	Gas Chromato graphy used to analyse different Raw materials and inprocess samples in Quality control	
2	**Equipment ID**	
2.1	Q1-GCS 01,02	
2.2	B1-GCS 01	
3	**Technical Specification**	
3.1	Model	cGLP
	Oven details (QC & HepB)	
3.2	Operating Tem Range	Ambient + 4 to 450
3.3	Retention time Repetability	<0.0008min
3.4	Peak area Repetability	RSD 1.0%
3.5	Temp Set point resolution	0.1°C
3.6	Temparature accuracy	0.1°C
3.7	Minimum number of cappilary colums	3 Nos
3.8	Temparature accuracy	0.01°C
3.9	Number of ramps/Plateu	Minimum 9 ramps 10 Plateu
3.10	Maximum Heating rate	120°C/min
3.11	Cooling speed	450° to 50°in 4 min
3.12	Quantity	1 No GC HS with autosampler and 1 No GC with manual injector
3.13	Dimensions (W x D x H) Internal Work area External dimensions	Vendor to specify
	Detectors Details (QC & HepB)	
3.13	Dectector	Flame Ionization detector
3.14	Temparature	Max 450°C
3.15	Minimum detected quantity	1.5 pgC/s (dodecane)
3.16	Dynamic range	10^7

3.17	Weigt of FID	Vendor to specify
3.18	Dimensions	Vendor to specify
	Injector details (QC & HepB)	
3.19	Number of Injectors	3 Nos
3.20	Split ratio	. 1:7500
	Auto sampler Details(For QC)	
3.21	Type	Fully automated liquid auto injector/auto sampler
3.22	Injection Range	1µL to 100.0µL
3.23	No of Sample Vial	Minimum 100 Nos of sample vials
3.24	Reproducability	1.0 % RSD or better
3.25	Syringe sizes& Speed	Compatable with varible syrizes and different speed
	Head Space Details(For QC)	
3.26	No of Sample Vial	Minimum 30 Nos
3.27	No of Vials in Incubator	Minimum 12 Nos
3.28	Vial Temp	Vial Temp. Up to 300 °C, Transfer line / Interface Temp. 350C (Preferable)
3.29	Gas Control	Electronic carrier gas Control & Vial pressurization with leak check
3.30	Sample line & sample Loop	Complete inert sample flow line with Sample Loop (1ml)
	Colums required (QC)	
3.31	Colum dimensions l = 30 m, Ø = 0.32 mm Colum material Fused Silica phase: poly[(cyanopropyl)(phenyl)][dimethyl]siloxane R (film thickness 1.8 µm) Provided	
3.32	Colum Dimension with size: l = 30 m, Ø = 0.53 mm;6 per cent polycyanolpropylphenyl siloxane and 94 per cent of polydimethylsiloxane provided	
3.33	Colum Dimension with size: l = 30 m, Ø = 0.53 mm;6 per cent polycyanolpropylphenyl siloxane and 94 per cent of polydimethylsiloxane provided	
3.34	Colum dimensions l = 30 m, Ø = 0.25 mm Colum material Fused Silica ,Statnory phase: macrogol 20 000 R (film thickness 0.25 µm).	
3.35	Colum dimensions l = 30 m, Ø = 0.32 mm Colum material Fused Silica ,Statnory phase: macrogol 20 000 R (film thickness 0.5 µm).	
3.36	Colum dimensions l = 30 m, Ø = 0.32 mm Colum material Fused Silica/Glass Statinory phase poly(dimethyl)siloxane R (film thickness 1.0 µm) provided	
3.37	Fused-silica capillary or wide-bore column 30 m long and 0.32 mm or 0.53 mm in internal diameter coated with cross-linked 6 per cent polycyanopropylphenylsiloxane and 94 per cent polydimethylsiloxane (film thickness: 1.8 µm or 3 µm).	
3.38	Fused-silica capillary or wide-bore column 30 m long and 0.32 mm or 0.53 mm in internal diameter coated with macrogol 20 000 R (film thickness: 0.25 µm),	

	Other Accessories	
3.39	Hamilton manual syringe provided	
3.40	He,H2,N2& Air gas Cylinder (1 No .each)	
3.41	*2-stage regulator for above gas cylinders.*	
3.42	*Gas Purification Panel.*	
4	**Material of Construction**	
4.1	Body	Stainlee steel corrosion resistant
4.2	Finishes	Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints
5	**Specific Equipment requirment**	
5.1	Printer port along with compatable printer provided	
5.2	The body construction shall provide tempearture stability.	
5.3	The equipment shall be compatible for cleaning with all standard disinfectants	
6	**Other Requirement**	
6.1	Training/Demo for the users on operation and cleaning to be provided.	
7	**Regulatory aspects**	
7.1	CE Certification	
8	**Safety requirements**	
8.1	Following facilities must be provided to protect personnel and equipment:	
8.2	Appropriate closure of all parts	
8.3	Proper earthing is necessary	
8.4	Noise level should be below 60 decible at a distance of 1m from the equipment	
9	**Documents**	
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file	
9.2	IOQ document.	
9.3	Operation and maintenance manuals shall be provided along with IOQ & PQ documents during installation at site	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	Warranty Letter for Minimum 1 year from the date of installation.	
9.6	Vendor should provide list of standard spare parts with ordering information.	
9.7	Vendor should provide list of change parts (if applicable) with ordering information	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Gas Chromatography	
	Document No.	DS-GCS 01	
	Revision No.	00	

10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Shimadzu,Agilent
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-GCS 01,02	Admin,QA and QC	Immuno chemical Lab	Q1S026	5360 X 5520	2400
B1-GCS 01	Hep-B	-	-	-	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
30-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: HPLC**

Document No.: DS-HPLC 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
~~Q1~~	~~Admin, QA & QC~~	~~Q1-HPLC 01~~	-	~~1 Set~~
B1	Hib	B1-HPLC 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	29-05-2017
Checked by			
Mr. Tushar Shende	Senior Engineer - Process	Tushar	29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		29.05.2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		07.06.2017
User department: Quality Control R. Abhaichaudari	DM		07-06-2017
Project / Engineering department VISHNU.S	AM		20.06.2017
Approved by			
Head of the department MBB V. Muralitharanam V. Murali	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department Quality Control Vasudeva Kumar. R	SM		22-06-2017
Head of the department (QA)	QAM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	HPLC	
	Document No.	DS-HPLC 01	
	Revision No.	00	

1	**Process requirements**	
1.1	HPLC (High-performance liquid chromatography) system for Analytical work	
2	**Equipment ID**	
2.1	Q1-HPLC 01, B1- HPLC 01	
3	**Technical Specification**	
3.1	Model	cGLP Model
3.2	Pump	Quaternary systems, Gradient Mode
3.3	Height	As per vendors specification
3.4	Weight	As per vendors specification
3.5	Power supply	AC 230V 50 Hz
3.6	Integration of Equipment	USB port, compatible with windows 7 or later version
3.7	Quantity	2 Nos. 1 nos
3.8	Type of finish	Non corrosive Non reactive, acid & solvent resistant
	Functional Specific Requirements	
3.9	Low dispersion fluidics	(< 650uL, independent of back pressure) to enhance fast gradients and rapid system equilibration
3.10	Programable Flow rate	Minimum 0.05 ml to 10 ml/min or higher end with 0.001 mL/min increment
3.11	Compressibility Compensation	Automatic and Continuous
3.12	Plunger Seal Wash	Integral, Active, Programmable.
3.13	System should have more than 10 or better no of Gradient Profile	Eleven available gradient curve profiles; linear, step, concave and convex for easy method development.
3.14	Maximum Operating Pressure	Approx at high range 300 bar
3.15	Pressure ripple	≤ 2.5%
3.16	Gradient range	Approx 0-100%
3.17	Gradient accuracy	Approx ± 0.5% (independent of Back Pressure)
3.18	Gradient precision	<0.15% RSD, 0.02min RSD, whichever is greater
3.19	Solvent Position	24 aqueous buffers or 12 aqueous buffers and 12 organic modifiers flushing and column equilibration
3.20	Automation	Generation of a Chem Station sequence; Experiment setups for multiple samples and injections; Settings can be stored as a template for reuse
3.21	Syringe size	1 ml and 2 ml
3.22	Flow accuracy	Approx < 1%

3.23	Flow precision	Approx ± 0.08% RSD
3.24	Solvent conditioning via four-channel high efficiency vacuum in-line degasser	Approx 4
3.25	Solvent Delivery System (Low Pressure mixing Quaternary Gradient Pumping System)	Low volume degassing chambers (< 500 uL) enhance rapid solvent change overs
3.26		System should have in-built system preparation for an automated software assisted purge function for ease of solvent changing and system purging/priming.
3.27		This HPLC System should be capable to run as fast HPLC system without modifying any hardware, with intelligent speed column or shorter column like 20mm length.
	Auto Sampler	
3.28	Auto Sampler mode	Sample should collect from Vials/microtiter plates Sample volume for taking 0.1-1000 µL inj. vol. Control through the parent software
3.29	Sample Compartment	Temperature of sample compartment : 0 - 60
3.30	Pressure	Approx upto 600 bar
3.31	Desirable (Optional)	Sample Injection System with - For Analytical injector Dual injector option, for 50/100/200 :l/ 100ps Analytical & Semi-prep analysis for semi preparative 5ml /100ps (Approx)
3.32	No of sample vials	120 sample capacity via industry-standard 2 mL vials configured in 5 x 24 vial carousels
3.33	No of injections	1 to 99 injections per sample vial
3.34	Sample delivery percision	Typically < 0.5% RSD (5 to 80 uL)
3.35	Lowest Sample carry over	<0.01% for Caffeine
3.36	Injection Needle Wash	Integral, Active, Programmable dynamic needle wash (i.e. no wash vial) minimizes sample carryover
3.37	Injection accuracy	+1ul (+2%)
3.38	Standard sample vial	2 mL
3.39	Sample temperature control	Ambient minus 25 °C or 4 °C whichever is greater to 40°C in 1°C increment
3.40	Injection volume range	Programmable injection volume range of 0.1 to 100 ul standard, with optional sample loop upto 2,000 uL
3.41	Injector linearity	>0.999 co efficient of deviation (1 to 100 µL)
3.42	Needle replacement	Tool-free replacement of needle wash frit
3.43		User- settable stat runs, auto additions and auto standards

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	HPLC	
	Document No.	DS-HPLC 01	
	Revision No.	00	

	Detector-1 (PDA)	
3.44	Source	Single beam polychromators, Source:Duterium and tungsten-halogen
3.45	Wavelength range	190-800 nm
3.46	Sensivity	0.01 to 2.0 AUFS
3.47	Wavelength Accuracy	±2 nm
3.48	Mode of Operation	Scanning and detection at variable/fixed wave length.
3.49	Noise specification	10 X 10-6AU, 10mm cell at 254nm or better
3.50	Drift specification	<1 X 10-3AU/hour or better
3.51	Detector Linearity	<5% at 2AU, 257 nm or better
3.52	Flow cell path length	10mm
3.53	Cell volume	<12 µl
3.54	Spectral Resolution	<1.2nm
3.55	Flexible sampling	rates up to 80Hz (data acquisition) for normal and fast LC separation
3.56	Detector Specification	Detector should operate in 2D and 3D more simultaneously
3.57		Inbuilt Software algorithm to keep Lamp energy always 100% throughout Lamp Life, to maximize Signal to Noise or to increase sensitivity
3.58		Detector should have suitable mechanism in flow cell to eliminate Refractive index effect, so as to get good peak shape with highest sensitivity
3.59		Detector should have peak purity algorithm for automatic correction for noise
	Detector-2 (UV)	
3.60	Wavelength	Complete UV-VIS range
3.61	Source	Deuterium and / or Tungsten
3.62	Noise	Aprox. ± 0.35x10-5 AU, dry cell 254 nm
3.63	Drift	Approx <2x10-4 AU/hr.
3.64	Linearity	Approx 5 nm
3.65	Accuracy	Approx. ± 1 nm
3.66	Reproducibility	Approx. ± 0.1 nm
3.67	Automation	Software and manual controls. The detector should have lamp optimization software, Variable Scanning and analysis facility
	Detector-3 (Refractive Index Detector)	
3.68	Refractive Index range	1.00 to 1.75 RIU
3.69	Flow rate	Approx. 0.2 ~ 0.3 ml/min
3.70	Noise Level	+ or - 1.5 X 10e (-9) RIU mode
3.71	Flow Cell	Fused Quartz

3.72	Flow cell Volume	10 Microlitre, Thermostatic
3.73	Drift	< or equal + or - 1.0 X 10e(-7) RIU /hour
3.74	Programmable	functions of range, auto Zero and auto purging
3.75	Automation	Automatic Back Pressure valve to protect flow cell,
3.76	Temperature Control	Approx Internal oven 30 C to 55 C
3.77	Sensitivity	1,2,4,...512,1024
3.78	Automation	Software and manual controls. The detector should have lamp optimization software, Variable Scanning and analysis facility
	Degasser	
3.79	Online/Inline	Vacuum degasser flow rate:,chanel :2 or 4 independent
3.80	Flow rate	Approx 0.2-5.0 ml/min or higher
	Column Heater	
3.81	Temperature Range	20Deg C to 65 Deg C (5 Deg above Ambient).
3.82	Temperature Setting Range	1 Deg C
	Chromatography data software	
3.83	Chromatography data software	Single point control of the entire HPLC Customizable data reports, online help wizards Report publisher/ Report can be stored at PDF format
3.84		Software should Control entire modules of HPLC system, acquire and process date.
3.85		Software Customized Sample analysis report publish.
3.86		Oracle database for better organization and easy retrieval or work and System user data.
3.87		Interactive control and display of solvent delivery
3.88		All functions and features accessible from a single window-use
3.89		The command bar to navigate
3.90		Wizards to simplify and automate common system functions.
3.91		Methods – instrument, processing and reporting parameters in one place.
3.92		Diagnostics functions and configuration wizards
3.93	Electrical Utilities	AC 230V 50 Hz
3.94	Computer	Suitable PC with soft ware provided by Vendor
3.95	Printer	Colour Laser printer

Equipment Specification Data Sheet						
HLL Biotech Limited, Chennai						
nne®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU				HBL
		Equipment Name	HPLC			
		Document No.	DS-HPLC 01			
		Revision No.	00			
4	Material of Construction					
4.1	Wetted surface material	All wetted parts SS 316 L				
4.2	Type of finish	Non corrosive Non reactive, acid & solvent resistant				
5	Other Requirement					
5.1	Training/Demo for the users on operation and cleaning to be provided.					
6	Regulatory aspects					
6.1	CE certification					
7	Safety requirements					
7.1	Following facilities must be provided to protect personnel and equipment:					
7.2	Appropriate closure of all parts					
7.3	Proper earthing is necessary					
7.4	Extensive diagnostics					
7.5	Complete system control with user friendly help and system diagnostics					
7.6	Error detection and display with audio visual alarm system for leak detection					
7.7	Built in system suitability as per USP/BP etc					
7.8	Safe leak handling, leak output signal, voltage fluctuation, process, temperature deviation					
8	Documents					
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file					
8.1	complete IQ,OQ,PQ documents for hardware and software(soft and hard copies)					
8.2	Operation and maintenance manuals shall be provided along with IOQ documents with trouble shooting tips (Both soft and Hard copies) during installation at site					
8.3	Compliance and Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.					
8.4	Warranty Letter for Minimum 1 year from the date of installation.					
8.5	Vendor should provide list of standard spare parts with ordering information.					
8.6	Vendor should provide list of change parts (if applicable) with ordering information					
8.7	Instrumentation and control wiring drawings, accessories and spare parts list, procedures for calibration and cleaning					
8.8	Accessories and spare parts list					
8.9	Procedures for calibration and cleaning					
9	GMP Requirements					
9.1	Validation services (IQ,OQ,PQ) compliance with complete qualification packages					
9.2	Early Maintenance feedback (EMF) for continuous tracking of instrument usage					

9.3	General compliance services
9.4	Hardware and system suitability
9.5	Usage, maintenance & error Log reports/records, system control license
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Waters, Agilent
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-HPLC 01	Admin, QA & QC	Instrumentation	Q1S020	6440X3465	2400
B1-HPLC 01	MBB-Hib	IPQC	BIG135	9m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Incubator**

Document No.: DS-INC 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Q1F	Mycoplasma	Q1F-INC 02-03	240 - 300	2
F4	BCG	F4-INC 02-07	800 - 1000	6
B1	MBB-HiB	B1-INC 02	200	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	29-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S. Shukla	29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		29-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control S. Aravindha Hari	DM	S. Aravindha Hari	07-06-2017
User department: BCG E. Jayavari	AM		07.06.2017
User department: MBB Anoop Kumar	AM		07-06-2017
Project / Engineering department VISHNU.S	AM	S. Vishnu	19-06-2017
Approved by			
Head of the department Quality Control Dr. Suresh Babu	DGM	Dr. Suresh Babu	23-06-2017
Head of the department BCG M. Subrahmanyam / V. Manitha	Head Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department MBB M. Subrahmanyam / V. Manitha	Head Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA) Dr. Suresh Babu	DGM	Dr. Suresh Babu	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet HLL Biotech Limited, Chennai					
nne®	INTEGRATED VACCINES COMPLEX,				HBL
	Equipment Name	Incubator			
	Document No.	DS-INC 02			
	Revision No.	00			
1	**Identification no**	**Volume in L**	**Table top/floor model**	**In built Data logging**	**Process requirements**
1.1	Q1F-INC 02-03	240 - 300	Vendor to specify	NA	The incubator shall be used for incubation of biological samples under controlled conditions.
1.2	F4-INC 02-07	800-1000	Vendor to specify	NA	
1.3	B1-INC 02	200	Vendor to specify	NA	
2	**Technical Specifications**				
2.1	Model	cGMP Incubator			
2.2	Type	Standard			
2.3	Utility (Compressed air/gas)	Vendor to specify			
2.4	Shelves	4-5 Nos (adjustable); Perforated SS 304 shelves			
2.5	Temperature range	ambient +5 to 75°C			
2.6	Temperature Readability	0.1°C			
2.7	Temperature Uniformity	± 0.6 °C @37 °C			
2.8	Temperature Controller	PID controller			
2.9	Display Unit	LCD			
2.10	Interlocking	Electromagnetic door interlocking			
2.11	Dimension (Chamber size,external size)	*As per the volume specified above*			
2.13	Quantity	9 nos			
2.14	Power Requirement	To be compatible to standard Indian power supply sockets			
3	**Material of Construction**				
3.1	External body Construction	cGMP Compliant exterior			
3.2	Internal body Construction	SS 304 (Electropolished)			
3.3	Inner Door	Safety transparent door			
3.4	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints c) All bolts, nuts on the exterior part of the equipment will be with cap head or cap nut			
3.5	Gaskets, seals, O-ring	Food Grade/ nontoxic material;			
3.6	Validation	Validation port to be provided to insert probes for temperature mapping			
3.7	All welds shall be ground finish				
4	**Specific Equipment Requirements**				
4.1	Shelf shall be of perforated type				
4.2	Microprocessor controller unit with PID for system control				

4.3	***Alarm : (Visual - Audio)*** 1. temperature over shoot of 2.5°C from set point 2. Alarm for prolonged door opening
4.4	RS-232 Computer Interface allows remote data logging and monitoring of the system
4.5	The heat given off by the unit must be stated (inside the room).
4.6	Temperature mapping to be provided at the time of installation
4.7	Temperature sensor (PT 100) should be provided.
4.8	Equipment shall be compatible for cleaning with all standard disinfectants
5	**Other Requirements**
5.1	Training/Demo for the users on the operation and cleaning to be provided.
5.2	Equipment should poses universal safety requirment.
6	**Regulatory Aspects**
6.1	DIN 12880 Class 3.1 (Temperature safety)
6.2	IEC 61010-1 (Electrical safety)
6.3	cGMP
6.4	CE certification
7	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
7.1	Noise level should be below 60 decible at a distance of 1m from the equipment
7.2	Chamber shall be insulated properly to maintain inner environment
7.3	Appropriate closure of all parts.
7.4	Proper Earthing is necessary.
8	**Documents**
	Following documents,but not limited to these,are experted from the vendor as part of the supply package in hard copy as well as editable electronic file.
8.1	IOQ Documents
8.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site
8.3	Warranty Letter for 1 year from the date of installation.
8.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9	**Timelines**
9.1	Not Applicable
10	**Preferred list of make**
10	Esco,Thermo scientific,Binder,Memmert,Eppendorf.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX,	
	Equipment Name	Incubator
	Document No.	DS-INC 02
	Revision No.	00

HBL HLL BIOTECH LIMITED

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-INC 02-03	Mycoplasma	Negative culture	Q1F021	18m2	2700
F4-INC 02-06	BCG	Incubator	F4G021	46m2	2700
F4-INC 07	BCG	Media bottle storage	F4G041	40m2	2700
B1-INC 02	MBB	Seed Lab	BIG109	18m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
17-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Inspissator**

Document No.: DS-INS 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F4	BCG QC	F4-INS 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	22-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S.Shede T.S.Shede	22.05.2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		22.05.2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department BCG V.V.VISHNUPRIYA	DM	V.V.Priya	06-06-2017
Project / Engineering department VISHNU.S	AM	S.	21-06-2017
Approved by			
Head of the department BCG	Dkrp		23-06-2017
Head of the department QA R. SURESH BABU	Dkrp	R. Suresh Babu	23-06-2017
Authorized by			
Project Authority	MA		

Technical Comparison Document			
HLL Biotech Limited, CHENNAI			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Inspissator	
	Document No.	DS-INS 01	
	Revision No.	00	

1	**Process Requirement**	
1.1	The inspissatior shall be used for inspissation of Lowstein Jensen media.	
2	**Equipment ID**	
2.1	Q1-INS 01	
3	**Technical Specification**	
3.1	Model	GMP/ GLP
3.2	Temperature control	Microprocessor with PID
3.3	Display	LED /LCD display shall be provided
3.4	Operating Temperature Range	80 to 85 °C
3.5	Temperature range	5 to 95 ^{0}C
3.6	Temperature Readability(Resolution)	0.1 ^{0}C
3.7	Number of trays	3 or more adjustable and perforated SS316L trays.
3.8	Inspissating Capacity	450 bottles in single layer.
3.9	Water Heaters	Two water heaters of about 1.5 kw each shall be provided.
3.10	Spare Heaters	Two spare heaters shall be provided additionally.
3.11	Air circulating fan	To be provided in the center of inner chamber.
3.12	Power supply	To be compatible to standard Indian Power supply socket.
3.13	Quantity	1 No.
3.14	Dimensions (W x D x H) Internal Work area External dimensions	Vendor to specify
4	**Material of Construction**	
4.1	External body Construction	Built of rust free stainless steel sheet with heavy duty roller wheels.
4.2	Internal body Construction	SS 316L/SS 304.
4.3	Inner Door	Safety transparent door and closed system,Alarming system included.
4.4	Outer Door	Fully insulated SS door with lock and handle
4.5	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp corners,
4.6	Gaskets, seals, O-ring	Food Grade/ nontoxic material like neoprene or better. Use of Asbestos is prohibited
4.7	Expected operational hours per day	6 hrs
4.8	Validation	Validation port shall be provided.

Technical Comparison Document		
HLL Biotech Limited, CHENNAI		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Inspissator	
	Document No.: DS-INS 01	
	Revision No.: 00	

5	**Specific Equipment Requirements**
5.1	Temperature mapping to be provided at the time of installation
5.2	The body construction shall provide tempearture stability.
5.3	The trays shall be removable from main unit for easy loading of media bottles.
5.4	Trays shall be positioned at an angle of 20 degree approx. to provide slope to media.
5.5	The total heatup time of Inspissator shall be less than 2.5 hours.
5.6	It shall have forced air circulation to achieve uniformity of conditions.
5.7	Inspissator shall include a safety thermostat.
5.8	There should be independent over-temperature safety protection.
5.9	It should have heavy duty roller wheels for stability and easy repositioning of inspissator
5.10	**Alarm : (Visual - Audio)** for temperature deviation
5.11	Equipment design must realize zero contamination.
5.12	The heat/noise level given off by the unit shall be stated (inside the room).
5.13	Vendor should provide four electrical sockets for accessories.
5.14	The equipment shall be compatible for cleaning with all standard disinfectants
6	**Other Requirement**
6.1	Training/Demo for the users on operation and cleaning to be provided.
7	**Regulatory aspects**
7.1	CE certification
8	**Safety Requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts
8.2	Proper earthing is necessary
8.3	Doors interlocking alarm (visual/ audio).
8.4	Noise level should be below 60 decible at a distance of 1m from the equipment
8.5	For user and operation safety,provide fixed cut-out fuse and miniature circuit breaker at the back of control unit.
9	**Documents**
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file

9.2	IOQ document.
9.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.5	Warranty Letter for Minimum 1 year from the date of installation.
9.6	Vendor should provide list of standard spare parts with ordering information.
9.7	Vendor should provide list of change parts (if applicable) with ordering information
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Zenith, Jintal and Grant.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-INS 01	QC	Chemical/Biochemical	Q1S022	6190X5465	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
17-01-2017	Sandeep Kumar	00	-	New Document

Equipment Specification Data Sheet	**Equipment Name: Inverted Fluorescence Microscope**
Document No.: DS-FMC 02	**Revision: 00**
Project No.: 120310	**Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1F	Mycoplasma	Q1F-FMC 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process		22-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process		22-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		22-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control V. LAKSHMIPRIYA	DM		06-06-2017
Project / Engineering department VISHNU.S	A.M		21-06-2017
Approved by			
Head of the department: Quality Control Sanjeev Kumar R	SM		22-06-2017
Head of the department (QA)			23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Inverted Fluorescence Microscope	
	Document No.	DS-FMC 02	
	Revision No.	00	

1	**Process requirements**	
1.1	It is used to analyse the various types of microbiological samples.Microscopes with an inverted-style frame are designed primarily for tissue culture applications and are capable of producing fluorescence illumination through an episcopic and optical pathway.	
2	**Equipment ID**	
2.1	Q1F-FMC 02	
3	**Technical Specification**	
3.1	Model	NA
3.2	Type	Fluorescence microscope (Binocular)
3.3	Optical system	Infinity Corrected system
3.4	Nose Pieces type	Sextopule
3.5	Eye pieces (F.O.V)	10X
3.6	Magnification	4X to 40X and More
3.7	Condensers	Working Distance:72 to 80 mm; Universal condenser with atleast 4 position turret to accommodate various phase/ DIC rings.
3.8	Interpupillary Distance	48mm to 75 mm
3.9	Fluorescence filter turret	Four or more position
3.10	Fluro chrome	FITC
3.11	Contrast methods	Bright field,phase contrast
3.12	Fluorescence light source	Halogen lamp, Mercury lamp (100W)
3.13	Objective	Should be operable with transmitted light and fluorescence. Fluorite/Semi apochromatic working objective 4X, 10X, 20X and 40X
3.14	Quantity	1 No.
3.15	Power required	Compatiable to standard indian power
3.16	PC and Monitor	System to include PC suiting the application.The system should include high end PC for all the above applications.PC configuration should be capable of operating above mentioned software.
3.17	Camera	Colour and monochromatic cooled camera to be attched on the microscope.minimum 5 megapixel
3.18	Operator Protection	Should have the arrangement to protect the operator from UV exposure.
4	**Material of Construction**	
4.1	Body	Ergonomic body with stain and particle resistant finish, antimicrobial coated

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: Inverted Fluorescence Microscope	
	Document No.: DS-FMC 02	
	Revision No.: 00	

5	**Specific Equipment requirment**
5.1	Binocular head should rotate 360° and inclined at 30° to 45° with interpupillary and dioptric adjustment.
5.2	Nose piece position should be, reversed, with knurled grip for easy operation. Should be smooth operation and with positive click stops.
5.3	Stage should be delivering a high level of fluid motion control and longevity. Motion must be controlled with a right-hand low-position coaxial control and it should be driven by a rack and pinion system.
5.4	Stage and Nose piece movement shall be motorized
5.5	The microscope should have two focusing knobs mounted together. The large knob should be for coarse focus adjustment. The smaller knob should be for fine focus adjustment.
5.6	Condenser: Bright field, Abbe N.A. 1.25 with iris diaphragm and swing out filter holder which shall be moved through rack pinion. The condenser unit to incorporate high efficiency optical system for optimum utilization of light from low to high magnification.
5.7	The fluorescence microscope should have provision for taking photos of the samples under analysis and shoud be compatible to be connected and viewed through PC. Microscope camera and software shall be offered from original equipment manufacturer for better synchronisation.
5.8	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.
5.9	Software should be compatible for multiple PC.
6	**Other requirement**
6.1	The instrument must be portable
6.2	Training /Demo for users on operation and cleaning to be provided.
6.3	Design of the equipment should enhance cleaning by providing minimum sharp corners.
6.4	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover unused instrumentopenings.
6.5	Cleaning cloth / paper should be provided to clean optical surfaces.
6.6	Optional Accessories:Co-Axial mechanical stage. Spare objectives, sub-stage Lamp for 220V.
7	**Regulatory aspects**
7.1	CE certification
8	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file
9.1	IOQ documents.

9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
9.5	List of standard spare parts with ordering information.
9.6	List of change parts (if applicable) with ordering information
10	**Timelines**
10.1	NA
11	**Preferred list of Makes**
11.1	Leica, Zeiss, Nikon, Olympus
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-FMC 02	Mycoplasma	Instrument Lab	QIF009	5450 x 2700	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Upright Microscope

Document No.: DS-UMC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	Hep-B	B1-UMC 02	-	1
B1	HiB	B1-UMC 03	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	31-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	for T.S. Sudev	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Dr. RADHA	DM		06-06-2017
Project / Engineering department VISHNU.S	AM	S. Vishnu	16-06-2017
Approved by			
Head of the department MBB Dr. Rekha V. Mehta	Head-Bacterial Vaccines	M.V. Subramanyam	22-06-2017
Head of the department (QA) Dr. JOGESH BABU	DGM	Dr. Jogesh Babu	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Upright Microscope	
	Document No.	DS-UMC 02	
	Revision No.	00	

1	**Process Requirements**	
1.1	B1-UMC 02 : Used to visualize and identify (under magnification) various types of micro organisms.	
1.2	B1-UMC 03 : Used for observing T25 cell culture flasks and cell count using hemocytometer.	
2	**Equipment ID**	
2.1	B1-UMC 02	
2.2	B1-UMC 03	
3	**Technical Specifications**	
3.1	Model	NA
3.2	Type	Binocular compound microscope with camera provision
3.3	Optical system	Infinitly Corrected system
3.4	Interpupillary distance	48mm - 70 mm
3.5	Quantity	2 Nos
3.6	Dimensions	Vendor to specify
3.7	Power requirement	To be compatible to standard indian Power supply sockets.
3.8	Light Source	White LED
4	**Material of Construction**	
4.1	Body	Ergonomic body with stain and particle resistant finish.
5	**Specific Equipment Requirements**	
5.1	Nose Piece should rotate 360° and Binocular head should be inclined at 30° to 45°.Features interpupillary and dioptric adjustment.	
5.2	Magnification of the microscope should be 4X,10X,40X and 100X.	
5.3	Nose piece position should be reversed with knurled grip for easy operation. Should features smooth operation with positive click stops.	
5.4	Stage: Fixed plane stage with specimen holder and should be provided X and Y movement.	
5.5	Stage should be delivering a high level of fluid motion control and longevity. Motion must be controlled with a right-hand low-position coaxial control and it should be driven by a rack and pinion system.	
5.6	Focusing movement should be coaxial, low-position coarse and fine focus controls; it should be graduated to 2 microns per division; fitted with safety autostop. Range should be ± 20mm	
5.7	The microscope should have two focusing knobs mounted together. The large knob should be for coarse focus adjustment. The smaller knob should be for fine focus adjustment.	
5.8	Condenser:Bright field, Abbe N.A. 1.25 with iris diaphragm and swing out filter holder which shall be moved through rack pinion. The condenser unit to incorporate high efficiency optical system for optimum utilization of light from low to high magnification.	
5.9	Holders: 35mm diameter petri dish holder, universal holder, glass slide holder,Haemocytometer holder.	
5.10	All external parts of the microscope should be disinfectable.	
5.11	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.	
5.12	White LED lamp for illumination shall be provided	
6	**Other Requirements**	
6.1	The instrument must be portable.	

6.2	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover when equipment not in use.
6.3	Cleaning cloth / paper should be provided to clean optical surfaces.
6.4	Accessories to be provided:Co-Axial mechanical stage, Draw tube, spare objectives, sub-stage with LED.
6.5	Training /Demo for the users on operation and cleaning to be provided.
7	**Regulatory Aspects**
7.1	CE certification.
8	**Safety Requirements**
	Following facilites must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
9	**Documents**
	Following documents, but not limited to these, should be supplied by the vendor as part of the supply package in hard copy as well as editable electronic file
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ Documents during installation at site.
9.3	Warrenty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instruments with respect to traceable national reference standard instruments and their calibration procedure.
10	**Timelines**
10.1	NA
11	**Preferred list of Makes**
11.1	Leica, Zeiss, Nikon, Olympus.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-UMC 02	MBB-Hep B	IPQC	B1G008	11m2	2700
B1-UMC 03	MBB-HiB	Seed Lab	B1G109	18m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
17-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Inverted Microscope

Document No.: DS-IMC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	Measles	R1-IMC 02-05	-	4

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	31-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S. Shukla	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MR Kuldip Mane	AM		12-06-2017
Project / Engineering department VISHNU.S	A.M	S. Cis	21-06-2017
Approved by			
Head of the department: MR DS. Ramanan	DVP		22-06-2017
Head of the department (QA) R. Anand Babu	DGM	A. Anand Babu	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Inverted Microscope	
	Document No.: DS-IMC 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	It is used for observing hemocytometer, 90 well plate,cell culture flasks, roller culture bottles and 10 layered cell factories/cell stacks.	
2	**Equipment ID**	
2.1	R1-IMC 02-05	
3	**Technical Specification**	
3.1	Model	NA
3.2	Type	Inverted microscope (Binocular)
3.3	Optical System	Infinity corrected system
3.4	Noise Pieces	Quadruple(Minimum)
3.5	Eye pieces (F.O.V)	10X
3.6	Magnification	4X to 40X
3.7	Condensers	Working Distance 72 mm to 80 mm.
3.8	Contrast Method	Bright field,Phase Contrast.
3.9	Quantity	4 Nos.
3.10	Power required	To be compatible with standard Indian power supply sockets.
4	**Material of Construction**	
4.1	Body	Ergonomic body with stain and particle resistant finish.
5	**Specific Equipment Requirements**	
5.1	Binocular head should rotate 360° and inclined at 30° to 45°. Features interpupillary and dioptric adjustment.	
5.2	Minimum magnification of the microscope should be 10X replace by 4X.	
5.3	The following specification should be provided : a) Illumination light - white LED/ Halogen. b) Focussing: Coaxial coarse/fine focusing. c)Tubes: Binocular tube (within main body). d) Holders: Petri Dish Holder, Universal Holder, Terasaki Holder ,Slide Glass Holder, Hemocytometer Holder. Stage: Fixed Plane stage and attachable mechanical stage to be provided and should have X and Y movement. e) the inverted microscope should be capable for observing cell culture flasks (T25,T75 and T175) roller culture bottles (850 cm^2 bottles with 110mm diameter) and 10 layered cell factories/cell stacks (Height = 19 cms) 96 well plate. f) All external parts of the microscope should be disinfectable.	
5.4	Nose piece position should be, reversed, knurled grip for easy operation. Should feature smooth operation and with positive click stops.	
5.5	Stage should be delivering a high level of fluid motion control and longevity. Motion must be controlled with a right-hand low-position coaxial control and it should be driven by a rack and pinion system.	

5.6	The microscope should have two focusing knobs mounted together.The large knob should be for coarse focus adjustment.The smaller knob should be for fine focus adjustment.
5.7	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.
5.8	Provision for Camera attachment should be provided.
5.9	Provision for epi fluorscence attachment should be provided.
5.10	Equipment shall be compatible for cleaning with all standard disinfectants.
6	**Other Requirements**
6.1	The instrument must be portable.
6.2	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover the equipment when not in use.
6.3	Cleaning cloth / paper should be provided to clean optical surfaces.
6.4	Accessories to be provided :Spare Fuses, Draw tube, spare objectives, sub-stage white LED Lamp.
6.5	Training /Demo for users on operation and cleaning to be provided.
7	**Regulatory aspects**
7.1	CE certification
8	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	Appropriate closure of all parts.
8.2	Proper earthing is necessary.
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.
9.3	Warranty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Leica, Zeiss, Nikon, Olympus
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
R1-IMC 02	Measles	Cell culture (Measles)	R1G071	3800X4500	2700

Equipment Specification Data Sheet HLL Biotech Limited, Chennai					
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED	
	Equipment Name	**Inverted Microscope**			
	Document No.	**DS-IMC 02**			
	Revision No.	**00**			
R1-IMC 03	Measles	Obsevation room	R1G057	4800X2095	2700
R1-IMC 04	Measles	Obsevation room	R1G094	3500X2350	2700
R1-IMC 05	Measles	Rubella Virus culture	R1G105	5900X2530	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Cryogenic storage container(LN2)

Document No.: DS-CSC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
R1	Measles	R1-CSC 02-09	-	~~8~~ 4 29.05.17

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Process Engineer		31-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	For T.S. Shukla	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation. Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MR Kuldip Mane	A.M.		12-06-2017
Project / Engineering department VISHNU.J	A.M		19.06.2017
Approved by			
Head of the department: MR S.R. KUMARAN	DVP		23-06-2017
Head of the department (QA)	DVP		28-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Cryogenic storage container(LN2)	
	Project #	120310	
	Document #	DS-CSC 02	

1	**Process requirements**	
1.1	The Cryo storage (LN2) container shall be used to cryopreserve cGMP cell banks for the purpose of manufacturing and testing vaccines.	
2	**Equipment ID**	
2.1	R1-CSC 02-09	
3	**Technical Specification for Cryogenic Storage Container**	
3.1	Model	cGMP compliant portable model
3.2	System Capability	Minimum 2000 vials
3.3	Storage Capacity	To store 1.2 ml, 2ml and 5 ml cryovials arranged in a secondary SS container
3.4	Sytorage Type	Manual loading of vials into the container
3.5	No.s of 2ml vials per canister/rack	Vendor to specify
3.6	Canister/Storage rack capacity	Vendor to specify
3.7	No.of. Canister/ rack	4 (minimum)
3.8	Static evaporation rate	Vendor to specify (with no product load)
3.9	Static Holding time	Minimum 80 days
3.10	Vessel exterior dimensions	Vendor to specify
3.11	Rack Dimension	Size should be suitable to store around 2000 vials of required capacity.
3.12	Quantity	~~8 nos~~ 4 Nos
3.13	Operational Parameters	Temperature : - 196 °C
3.14	Storage requirements	a) Provision to ensure that cryovials are stored at vapour phase of nitrogen with physical separation from contact with liquid nitrogen. b) The cryo storage container should be designed to store and retrieve 1.2 ml, 2ml and 5 ml cryovials arranged in a secondary SS container
4	**Material of Construction**	
4.1	cGMP compliant	
5	**Specific Equipment requirment**	
5.1	Should have easy access to the stored vials	
5.2	Should have full width top opening, compatible/suitable for storing and retrieving secondary SS containers containing the cryo-vials	
5.3	"Castor wheels"- should be made of heavy duty cGMP compliant material.	
5.4	Should be suitable to be comfortably transported, placed and operated in the specified area	

6	**Other requirement**
6.1	Vendor should quote for all critical spares and accessories such as (i.e not limited to) SS square shaped canister racks, storage inventory system such as SS cryo boxes for 2ml cryovials, LN2 transfer hose, cryoprotective gloves and safety goggles which should be provided with each equipment.
7	**Regulatory guidelines/Standards**
7.1	CE certification
8	**Safety requirements**
8.1	Container opening should be lockable to prevent unauthorized usage
9	**Documents**
9.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
9.2	MOC certficates for all the metallic and non metallic parts are required
9.3	IQ, OQ documentation
9.4	Surface finish certficates
9.4	Leak test for LN2 and Vacuum certificates
9.5	Certificate of confirmity to confirm whether the required specification are met (validation document)
9.6	Test certficates and calibration certificates
9.7	Certification: CE (European Confirmity) certfication
9.8	Warranty for vacuum and equipment should be separately mentioned
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Thermo Fisher Scientific,MVE,STATE BOURNE,Cryogenics,Marathon
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
R1-CSC 02-09	Measles	LN2 Storage	R1G083	4350X4150	2700

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED
	Equipment Name	Cryogenic storage container(LN2)		
	Project #	120310		
	Document #	DS-CSC 02		

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer with heating

Document No.: DS-MGH 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F4	BCG	F4-MGH 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	24-05-2017
Checked by			
Mr. Yogesha M J	Engineer - Process	For T.S.Shetty T.S.Shetty	24-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish	Amrutam	24-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: BCG Bulk Elayavan	AM	Elay	07-06-2017
Project / Engineering department VISHNU.S	A.M	S.	19-06-2017
Approved by			
Head of the department BCG Bulk Dr. Subrahmanyam V, Manikya	Head-Bacterial Vaccine	M.V. Subrahmanyam	22-06-2017
Head of the department (QA)	DGM		22-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Magnetic Stirrer with heating	
	Document No.: DS-MGH 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	The Magnetic stirrer will be used for uniform mixing and heating of product in glass bottle	
2	**Equipment ID**	**Capacity**
2.1	F4-MGH 02	To hold 1X20 L glass bottle/ unit of dia 300 mm
3	**Technical Specification**	
3.1	Model	Table top cGMP, with heating
3.2	Dimension (W X D X H, mm)	Vendor to specify based on above mentioned capacities.
3.3	Features	Flat Surface LED display and timer required
3.4	Stirring volume, max	One unit of equipment to hold and operate with full capacity of 1 X 20 liter glass bottle.
3.5	Stirring speed	0-1000 RPM for 20 L
3.6	Temperature Range	Ambient to 200 °C with heat control accuracy of ±5 °C
3.7	Display	LED Display
3.8	Power requirement	To be compatible to standard Indian Power Supply socket
3.9	Quantity	1No
4	**Material of Construction**	
4.1	Top plate	SS 304; Flat surface
4.2	Outer body	cGMP compliant
5	**Specific Equipment requirement**	
5.1	The external surface of the equipment should be easily disinfectable with standard disinfectants, and resistant to corrosion and chemicals. Stirrer should have smooth corners for easy cleaning	
5.2	Vibrations produced by the equipment during operation should be nil or minimum and should be specified by the vendor.	
5.3	Auto restart to set values upon power failures	
5.4	High magnetic adhesion preventing decoupling of stir bars	
6	**Other requirement**	
6.1	Standard accessories: 5 No.s PTFE coated magnetic stirring bars suitable to 20L to be provided for each equipment.	
6.2	PTFE withdrawal system for magnetic stirring bars to be provided for each equipment	
6.3	Training/Demo for users on operation and cleaning to be provided.	
7	**Regulatory aspects**	
7.1	CE certification	
8	**Safety requirements**	
	Following facilities must be provide to protect for personnel and equipment:	
8.1	Proper earthing should be provided.	
8.2	No sharp edges/ corners, crevices, pin holes in the equipment.	
8.3	Appropriate closure of all parts	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Magnetic Stirrer with heating	
	Document No.: DS-MGH 02	
	Revision No.: 00	

9	**Documents**
	Following documents, but not limited to these,are expected from the vendor as part of the supply package in the hard copy as well as editable electronic file
9.1	IOQ documents
9.2	Operations and maintenance manual shall be provided along with IOQ documents during installation at site
9.3	Warranty letter for 1 year from the date of supplpy.
9.4	Material test certificates
9.5	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.6	List of standard spare parts with ordering information
10	**Timelines**
10.1	Not applicable
11	**Preferred list of Makes**
11.1	IKA,Mettler Toledo, Sartorious, Thermo scientific
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F4-MGH 02	BCG	Media prepn	F4G009	6800 X 3940	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Magnetic Stirrer**

Document No.: DS-MGS 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F4	BCG	F4-MGS 02-03	-	2
R1	Measles	R1-MGS 02-04	-	3
B1	MBB (Hib)	B1-MGS 02-12	-	1
B1	MBB (Hep-B)	B1-MGS 02	20L	11

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		31-05-2017
Checked by			
Mr. Yogesha M J	Engineer - Process	For T.S. Shetty	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Bacterial Bulk	DM		12-06-2017
User department: BCG Bulk	AM		12-06-2017
User department: MR Kuldip Mane	AM		12-06-2017
Project / Engineering department VISHNU.S	AM		21-06-2017
Approved by			
Head of the department Bacterial Bulk	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department BCG Bulk	Head-Bacterial Vaccine	M.V. Subrahmanyam	22-06-2017

nne®		HBL HLL BIOTECH LIMITED	
Equipment Specification Data Sheet		**Equipment Name: Magnetic Stirrer**	
Document No.: DS-MGS 02		**Revision: 00**	
Project No.: 120310		**Project Name:** Integrated Vaccines Complex, Chengalpattu	
Head of the department MR Dr. R. KUMARAN			22-06-2017
Head of the department (QA) Dr. Suresh Babu		Dr. Suresh Babu	23-06-2017
Authorized by			
Project Authority	N/A		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Magnetic Stirrer	
	Document No.: DS- MGS 02	
	Revision No.: 00	

1	**Process requirements**	
1.1	The Magnetic stirrer will be used for uniform mixing of product in glass bottle.	
2	**Equipment ID**	**Capacity**
2.1	F4-MGS 02-03	to hold 1X15 & 1x5 L glass bottle/ unit of dia 300 mm
2.2	R1-MGS 02-04	to hold 1X20 L glass bottle/ unit of dia 300 mm
2.3	B1-MGS 02-12	to hold 1X50 L glass bottle/ Carboy unit of dia 400 mm
3	**Technical Specification**	
3.1	Model	Table top cGMP, without heating
3.2	Dimension (W X D X H, mm)	Vendor to specify based on above mentioned capacities.
3.3	Features	Flat surface,for 20 L capacity LED display and timer required
3.4	Stirring volume ,max	One unit of equipment to hold and operate with full capacity of 1 X 20 liter glass bottle.
3.5	Stirring speed	0-1000 RPM for 20 L; 100-1500 RPM for 5 L
3.6	Operating Temperature	4°C - 37°C
3.7	Power requirement	To be compatible to standard Indian Power Supply socket
3.8	Number of stirring positions	one
3.9	Speed control	Vendor to specify
3.10	Quantity	17 Nos.
4	**Material of Construction**	
4.1	Top plate	SS 304; Flat surface
4.2	main body	cGMP compliant
5	**Specific Equipment requirement**	
5.1	The external surface of the equipment should be resistant to corrosion and chemicals. Stirrer should have smooth corners for easy cleaning.	
5.2	Vibration produced by the equipment during operation should be nil or minimum and should be specified by the vendor.	
5.3	High magnetic adhesion preventing decoupling of stir bars	
5.4	Auto restart to set values upon power failures	
6	**Other requirement**	
6.1	Standard accessories : 5 No.s PTFE coated magnetic stirring bars suitable to the capacities (5L and 20L) to be provided with each equipment.	
6.2	PTFE withdrawal system for magnetic stirring bars to be provided for each equipment	
6.3	Training/Demo for users on operation and cleaning to be provided.	
7	**Regulatory aspects**	
7.1	CE certification	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: Magnetic Stirrer	
	Document No.: DS- MGS 02	
	Revision No.: 00	

8	**Safety requirements**
	Following facilities must be provide to protect for personnel and equipment:
8.1	Proper earthing should be provided.
8.2	Appropriate closure of all parts.
8.3	No sharp edges/ corners, crevices, pin holes in the equipment.
9	**Documents**
	Following documents, but not limited to these,are expected from the vendor as part of the supply package in the hard copy as well as editable electronic file
9.1	IOQ documents
9.2	Operations and maintenance manual shall be provided along with IOQ documents during installation at site shall be provided
9.3	Warranty letter for 1 year from the date of supply.
9.4	Material test certificates
9.5	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.6	List of standard spare parts with ordering information
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	IKA,Mettler Toledo, Sartorious, Schimadzu
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F4-MGS 02	BCG	Harvest&Purification	F4G021	42m2	2700
F4-MGS 03	BCG	Vial filling area	F4G040	111m2	2700
R1-MGS 02	Measles	Media Prpn room	R1G042	5400X8095	2700
R1-MGS 03-04	Measles	Cell Culture-1	R1G071	3800X4500	2700
R1-MGS 03	Measles	Disinfectant Preparation	F2G024	2380 X 4910	2700
B1-MGS 02-04	MBB	Polysaccahride purification room	B1G136	58m2	2700
B1-MGS 05-07	MBB	Conjugation& Purification	B1G133	43m2	2700

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED	
	Equipment Name	Magnetic Stirrer			
	Document No.	DS- MGS 02			
	Revision No.	00			
B1-MGS 08-10	MBB	Media Prpn room	B1G118	38m2	2700
B1-MGS 11	MBB	Buffer Staging room	B1G124	10m2	2700
B1-MGS 02	MBB-HepB	Media Prpn room	BIG019	44m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Niharika Ruhela	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Micro Aerophilic Condition Incubator

Document No.: DS-MAINC 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Q1F	Mycoplasma	Q1F-MAINC 01-02	150-170	2

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	24-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process	Tshende	24-05-2017
Approved by			
Mr.Krishna Amrutam	Manager - Formulation, Fill & Finish	Amrutam	24-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control V. LAKSHMIPRIYA	DM	V. Lpriya	06-06-2017
Project / Engineering department VISHNU. T	AM	J. Vishnu	19-06-2017
Approved by			
Head of the department Quality Control Sanjeev Kumar. R	SM	Sanjeev	20-06-2017
Head of the department (QA) M. PRAGATH BABU	Mgr	M. Pragath Babu	21-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: Micro Aerophilic Condition Incubator	
	Document No.: DS-MAINC 01	
	Revision No.: 00	

1	**Process requirements**	
1.1	The incubator shall be used for incubation of biological samples under controlled conditions.	
2	**Equipment ID**	
2.1	Q1F-MAINC 01-02	
3	**Technical Specifications**	
3.1	Model	cGMP Incubator
3.2	Type	Standard
3.3	Utility (Compressed air/gas)	Co2,N2
3.4	Shelves	3-5 Nos (adjustable); prefrebly Perforated SS 304 shelves or better
3.5	Temperature range	5°C- 50°C
3.6	Temperature control	± 0.1°C
3.7	Temperature Uniformity	± 0.3 °C
3.8	Temperature Controller	Vendor to Specify
3.9	Jacket Type	Air Jacketed System
3.10	Heat Type	Direct heat
3.11	CO2 Range	1% to 20 %
3.12	CO2 Sensor	IR
3.13	CO2 Controlability	± 0.15%
3.14	Humidity Delivery Sysytem	Vendor to Specify
3.15	Relative Humidity of the Chamber	95±5%
3.16	Alarm System	Vendor to Specify
3.17	O2 Range	1 - 21%
3.18	O2 Sensor	IR
3.19	O2 Controlability	± 0.15%
3.20	Data Output	Vendor to Specify
3.21	Sterilization Cycle Temperature	180 °C
3.22	Sterilization Cycle duration	Less than 12 Hours
3.23	Disinfection Time	Vendor to Specify
3.24	Display Unit	LCD or Better
3.25	Interlocking	Electromagnetic door interlocking
3.26	Dimension (Chamber size,external size)	As per the volume specified above

3.27	Quantity	2 nos
3.28	Power Requirement	To be compatible to standard Indian power supply sockets
4	**Material of Construction**	
4.1	External body Construction	cGMP Compliant exterior
4.2	Internal body Construction	SS 304 (Electropolished) or Better
4.3	Inner Door	Safety transparent door
4.4	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints c) All bolts, nuts on the exterior part of the equipment will be with cap head or cap nut
4.5	Gaskets, seals, O-ring	Gasket - Silicon ,Seals &O rings - Food Grade/ nontoxic material;
4.6	Validation	Validation port to be provided to insert probes for temperature mapping
4.7	All welds shall be ground finish	
5	**Specific Equipment Requirements**	
5.1	Shelf shall be of perforated type	
5.2	Microprocessor controller unit with PID for system control	
5.3	***Alarm System (Audio-Visual)***	1. temperature over shoot of 2.5°C from set point
5.4		2. Alarm for prolonged door opening
5.5	RS-232 Computer Interface allows remote data logging and monitoring of the system	
5.6	The heat given off by the unit must be stated (inside the room).	
5.7	Temperature mapping to be provided at the time of installation	
5.8	Temperature sensor (PT 100) should be provided.	
5.9	Equipment shall be compatible for cleaning with all standard disinfectants	
6	**Other Requirements**	
6.1	Training/Demo for the users on the operation and cleaning to be provided.	
6.2	Equipment should poses universal safety requirment.	
7	**Regulatory Aspects**	
7.1	DIN 12880 Class 3.1 (Temperature safety)	
7.2	IEC 61010-1 (Electrical safety)	
7.3	cGMP	
7.4	CE certification	
8	**Safety requirements**	
8.1	Following facilities must be provided to protect personnel and equipment:	
8.2	Noise level should be below 60 decible at a distance of 1m from the equipment	
8.3	Chamber shall be insulated properly to maintain inner environment	

8.4	Appropriate closure of all parts.
8.5	Proper Earthing is necessary.
9	**Documents**
9.1	Following documents,but not limited to these,are experted from the vendor as part of the supply package in hard copy as well as editable electronic file.
9.2	IOQ Documents
9.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site
9.4	Warranty Letter for 1 year from the date of installation.
9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of make**
11.1	Esco,Thermo scientific,Panasonic,Memmert,Binder
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-MAINC 01-02	Mycoplasma	Negative culture	Q1F021	18m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable					

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: RT PCR

Document No.: DS-RT PCR 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1F	Mycoplasma	Q1F-RT PCR 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		23-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process		23.05.2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		23-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control VIJAYA HMIPRIYA	DM		06.06.2017
Project / Engineering department VISHNU.J	A.M		20.06.2017
Approved by			
Head of the department Quality Control SANJEEV KUMAR.R	SM		22.06.2017
Head of the department (QA) R. SUBASH BABU	DGM		23.06.2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	RT PCR	
	Document No.	DS-RT PCR 02	
	Revision No.	00	

1	**Process requirements**	
1.1	Real Time PCR machine will be used to perform real time amplification of DNA/RNA samples by polymerase chain rection. Real Time PCR machine is to be supported with PC with inbuilt software for data analysis.	
2	**Equipment ID**	
2.1	Q1F-RT PCR 02	
3	**Technical Specification**	
3.1	Block format	to hold 96 samples
3.2	Reaction volume	20 to 50µl reaction volume
3.3	Dynamic Range:	10 orders of magnitude/9 logs
3.4	Temperature Range:	ambient to 99
3.5	Temperature Uniformity:	±0.50°C
3.6	Temperature Ramp Rate:	up to 2.5°C/second
3.7	Heated lid temperature	100 °C for peltier based thermo cycler
3.8	Multiplexing capabilities:	2 to 5
3.9	Sensitivity	to detect 1 copy of target sequence
3.10	Heating/ cooling method	peltier based or rotary format
3.11	Excitation source:	Tungsten-halogen lamp or LED
3.12	Detector:	CCD/photodiodes/photomultiplier
3.13	Memory (Storage of programs and Program runs)	on board- vendor to specify
3.14	Dimension,mm	vendor to specify
3.15	Power Requirement	to be compatible for standard Indian Power Socket
3.16	Weight	vendor to specify
3.17	Quantity	2 Nos.
4	**Material of Construction**	
4.1	MOC	vendor to specify

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: RT PCR	
	Document No.: DS-RT PCR 02	
	Revision No.: 00	

5	**Specific Equipment requirement**
5.1	Equipment shall facilitate easy cleaning and maintanance with standard disinfectant
5.2	PC based result viewing and interpretation of results. Hence standalone PC and UPS to be provided with inbuilt software.
5.3	Software to control the instrument operation, and collect and analyze the data generated
5.4	Suitable to run experiment based on Taqman probe, Sybr green assay
6	**Other requirement**
6.1	Training and demo for user on operation and cleaning to be provided
6.2	Software to support Multiplex analysis Up to 2 targets per well, Data analysis of PCR quantification through standard curve; melt curve analysis; gene expression analysis by relative quantity, end point analysis, etc
6.3	Consumable and accesseries to be provided with the machine, along with ordering information.
7	**Regulatory aspects**
7.1	CE Certification
7.2	21 CFR Part 11
8	**Safety requirements**
	Following facilities must be provided to protect personnel and equipment:
8.1	The equipment should be integrated with audio or visual alarm in case of any failure/errors
8.2	Appropriate clousure of all parts
8.3	Proper earthing is neccesery
9	**Documents**
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ Documents during installation at site.
9.3	warranty certificate for one year from date of supply.
9.4	Calibration certificate of critical instruments with respect to the tracable national reference standard instrument and their calibration procedure.
9.5	Vendor should provide list of standard spare parts with ordering information.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	AB, BIORAD, QUAIGEN
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: RT PCR	
	Document No.: DS-RT PCR 02	
	Revision No.: 00	

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-RT PCR 01	Mycoplasma	Instrument lab	Q1F009	16m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Niharika Ruhela	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)

Equipment Specification Data Sheet

Equipment Name: pH Meter and conductivity meter (Benchtop)

Document No.: DS-PHM 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB	B1-PHM-02-05	-	4
F4	BCG	F4-PHM-02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	29-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S. Shukla	29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & finish	Amrutam	29-05-2017

nne®

HBL HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited, A Government of India Enterprise)

Equipment Specification Data Sheet

Equipment Name: pH Meter and conductivity meter (Benchtop)

Document No.: DS-PHM 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Bacterial Formulation S.H. RAJESH MBB	DM		02-06-2017
User department: Rabies Bulk BCG Chaparala	AM		07-06-2017
User department: Animal House	NA	NA	NA
Project / Engineering department VISHNU.J	A.M	J. Vishnu	19-06-2017
Approved by			
Head of the department Bacterial Formulation Dr. SUBRAHMANYAM V MANDYA	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department Rabies Bulk BCG Dr. Subrahmanyam V Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department Animal House	NA	NA	NA
Head of the department (QA) J. SURESH BABU	DQM	J. Suresh Babu	23-06-17
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	pH Meter and conductivity meter (Benchtop)	
	Document No.	DS-PHM 02	
	Revision No.	00	

1	**Process requirements**	
1.1	To determine the pH and conductivity of the liquid samples.	
2	**Equipment ID**	
2.1	B1-PHM 02-05	
2.2	F4-PHM 02	
3	**Technical Specification**	
3.1	Type	Digital, benchtop type with inbuilt printer
3.2	Model	Basic cGLP waterproof model, combined glass electrode with supporting stand
3.3	Display type	pH, temperature,Conductivity 4 digit LCD with back light
3.4	pH range	0.00 - 14.00
3.5	pH Resolution and Accuracy	Resolution:-0.1, 0.01, 0.001 Voltage range, ± 1200 mV, Accuracy ± 0.01%
3.6	Conductivity range	0.001 to 999999µS/cm
3.7	Conductivity Resolution and Accuracy	Resolution:- 0.01 µS to 0.1 mS Accuracy ± 0.05%
3.8	Temperature range	- 5 to 105 °C
3.9	Temperature resolution and Accuracy	Resolution: 0.1 °C, Accuracy: ± 0.1 °C
3.10	Calibration	minimum 3 points upto 6 points
3.11	Expected operational hours per day	24 hrs with stand-by mode
3.12	Power requirement	To be compatible to standard Indian power supply socket
3.13	Quantity	5 Nos
4	**Material of Construction**	
4.1	Glass Electrode	The glass electrode must be made from Borosilicate glass for pH probe and conductivity probe.
4.2	Body of the meter	Powder coated or Vendor to specify
5	**Specific Equipment requirement**	
5.1	The pH & Conductivity meter must be microprocessor based precision with automatic temperature compensation and digital interface.	
5.2	The meter must have, stand with flexible arm, Electrode holder and universal power adaptor.	
5.3	Simultaneous measurement of pH and temperature	

5.4	Instrument should be capable of Multipoint calibration with max. 3 buffers as per USP ranges.
5.5	Ready made buffer solution of 4,7,10 and Conductivity to be provided - One set
5.6	Automatic temperature compensation for pH measurements.
5.7	LCD display to show the pH,Conductivity and temperature readings, audible beep indication during valid key operation.
5.8	Expanded memory to store and recall minimum upto 50 data sets, calibration data with date and time, calibration reminder alarm.
5.9	PH & Conductivity Spare electrode to be provided
5.10	The equipment shall be compatible for cleaning with all standard disinfectants.
6	**Other requirement**
6.1	Power: AC adapter, AA batteries (optional)
6.2	Interface: USB or RS 232 for data collection
6.3	should have a in-built printer for on the spot printing ex. pH,Conductivity, temperature, date and time intervals
6.4	Easy and convinient to operate, printing condition by pressing buttons on the equipment
6.5	Training/ demo for users on operations shall be provided.
6.6	Thermo paper rolls with the all accessories of pH meter should be supplied.
7	**Regulatory aspects**
7.1	CE Certification
8	**Safety requirements**
	Following facilites must be provided to protect personnel and equipment:
8.1	Proper earthing is necessary
8.2	Appropriate closure of all parts.
8.3	On power failure equipment should come in failsafe condition
9	**Documents**
	Following documents, but not limited to these, should be supplied by the vendor as part of the supply package in hard copy as well as editable electronic file
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at the site
9.3	Warrenty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure
9.5	NPL traceable Calibration certificates and calibration procedures

10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Mettler Toledo, Thermofischer Scientific, E & H
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-PHM 01	MBB-HepB	Fermentation	B1G007	154m2	2700
B1-PHM 02	MBB-HepB	Adsorption&Desorption	BIG040	58m2	2700
B1-PHM 03	MBB-HepB	Media Preparation	BIG019	44m2	2700
B1-PHM 04	MBB-HepB	Wash	BIG026	32m2	2700
F4-PHM 01	BCG	Media Preparation	F4G009	54m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: pH Meter (Benchtop)**

Document No.: DS-PHM 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1F	Mycoplasma	Q1F-PHM 02	-	1
R1	Measles	R1-PHM 02	-	1
B1	MBB-HiB	B1-PHM 02-07	-	6

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		29-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process		29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		29-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control	DM		07-06-2017
User department: MR K. Radhakrishnan	Manager.		07-06-2017
User department: MBB Anoop Kumar	AM		07-06-2017
Project / Engineering department VISHNU. S	AM		19-06-2017
Approved by			
Head of the department Quality Control	DGM		23-06-2017
Head of the department MR R. KUMARAN	DVP		
Head of the department MBB V. Manikandan	Head - Bacterial Vaccines	M V Subrahmanyam	22-06-2017
Head of the department (QA)	DGM		23-06-2017
Authorized by			
Project Authority	MA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	pH Meter (Benchtop)	
	Document No.	DS-PHM 02	
	Revision No.	00	

1	**Process requirements**	
1.1	To determine the pH and conductivity of the liquid samples.	
2	**Equipment ID**	
2.1	Q1F-PHM 02	
2.2	R1-PHM 02	
2.3	B1-PHM 02-07	
3	**Technical Specification**	
3.1	Type	Digital, benchtop type with inbuilt printer
3.2	Model	Basic cGLP waterproof model, combined glass electrode with supporting stand
3.3	Display type	pH, temperature,Conductivity 4 digit LCD with back light
3.4	pH range	0.00 - 14.00
3.5	pH Resolution and Accuracy	Resolution:-0.1, 0.01, 0.001 Voltage range, ± 1200 mV, Accuracy ± 0.01%
3.8	Temperature range	- 5 to 105 °C
3.9	Temperature resolution and Accuracy	Resolution: 0.1 °C, Accuracy: ± 0.1 °C
3.10	Calibration	minimum 3 points upto 6 points
3.11	Expected operational hours per day	24 hrs with stand-by mode
3.12	Power requirement	To be compatible to standard Indian power supply socket
3.13	Quantity	8 Nos.
4	**Material of Construction**	
4.1	Glass Electrode	The glass electrode must be made from Borosilicate glass for pH probe and conductivity probe.
4.2	Body of the meter	Powder coated or Vendor to specify
5	**Specific Equipment requirement**	
5.1	The pH meter must be microprocessor based precision with automatic temperature compensation and digital interface.	
5.2	The pH meter must have, stand with flexible arm, Electrode holder and universal power adaptor.	
5.3	Simultaneous measurement of pH and temperature.	
5.4	Instrument should be capable of Multipoint calibration with max. 3 buffers as per USP ranges.	
5.5	Ready made buffer solution of 4,7,10 to be provided - One set	

5.6	Automatic temperature compensation for pH measurements.
5.7	LCD display to show the pH and temperature readings, audible beep indication during valid key operation.
5.8	Expanded memory to store and recall minimum upto 50 data sets, calibration data with date and time, calibration reminder alarm.
5.9	Spare pH electrode to be provided.
5.10	The equipment shall be compatible for cleaning with all standard disinfectants.
6	**Other requirement**
6.1	Power: AC adapter, AA batteries (optional)
6.2	Interface: USB or RS 232 for data collection
6.3	pH meter should have a in-built printer for on the spot printing ex. pH, temperature, date and time intervals
6.4	Easy and convinient to operate, printing condition by pressing buttons on the equipment
6.5	Training/ demo for users on operations shall be provided.
6.6	Thermo paper rolls with the all accessories of pH meter should be supplied.
7	**Regulatory aspects**
7.1	CE Certification
8	**Safety requirements**
	Following facilites must be provided to protect personnel and equipment:
8.1	Proper earthing is necessary
8.2	Appropriate closure of all parts.
8.3	On power failure equipment should come in failsafe condition
9	**Documents**
	Following documents, but not limited to these, should be supplied by the vendor as part of the supply package in hard copy as well as editable electronic file
9.1	IOQ documents.
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at the site
9.3	Warrenty letter for 1 year from the date of supply.
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure
9.5	NPL traceable Calibration certificates and calibration procedures
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Mettler Toledo, Thermofischer Scientific, E & H
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment Name: pH Meter (Benchtop)	
	Document No.: DS-PHM 02	
	Revision No.: 00	

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1F-PHM 02	Mycoplasma	Q1F014	Material Prepn	26m2	2700
R1-PHM 02	Measles	R1G042	Material Prepn	5400X8095	2700
B1-PHM 02	MBB-HiB	BIG106	Fermentation&Harvest	128m2	2700
B1-PHM 03	MBB-HiB	BIG136	Purification room	58m2	2700
B1-PHM 04	MBB-HiB	BIG133	Conjugation	43m2	2700
B1-PHM 05	MBB-HiB	BIG118	Material Prepn	38m2	2700
B1-PHM 06	MBB-HiB	BIG124	Buffer Staging	10m2	2700
B1-PHM 07	MBB-HiB	BIG125	Wash room	26m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Niharika Ruhela	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Refrigerated Shaker Incubator

Document No.: DS-RSIB 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB (Hep-B)	B1-RSIB 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	30.05.2017
Checked by			
Mr. Yogesha M J	Process Engineer	For T.S. Shukla	30.05.2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		30.05.2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB CH RAJESH	DM		06-06-2017
Project / Engineering department VISHNU. J	AM	J.	16-06-2017
Approved by			
Head of the department: MBB Dr Manikka	Head-Bacterial Vaccines	M.V. Subramanyam	22-06-2017
Head of the department (QA) R. RAGESH BABU	DGM	Dr. Ragesh. R. Babu	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chengalpattu			
nne®	INTEGRATED VACCINES COMPLEX		HBL HLL BIOTECH LIMITED
	Equipment Name	Refrigerated Shaker Incubator	
	Project #	120310	
	Document #	DS-RSIB 01	

1	**Process requirements**	
1.1	A shaker incubator is a laboratory instrument used to agiate a biological samples (Microbial culture) by shaking while maintaining optimal environmental conditions.	
2	**Equipment ID**	
2.1	B1-RSIB 01	
3	**Technical Specification**	
3.1	Model	Floor Mounted/Table top with static shelves cGMP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Display	LCD, Large easy to read display clearly indicates speed, running time, alarm condition and temperature character.
3.4	Tempaerature Range	Ambient +5 °C to 60 °C and should CFC/HCFC free (cGMP compliant).
3.5	Temperature Resolution	0.1 °C
3.6	Temperature Uniformity	0.2 °C
3.7	Temperature Control Accuracy	± 1°C of set temperature
3.8	Shaking Range	25 to 300 RPM
3.9	Shaking accuracy	± 20 rpm
3.10	Shaking Platform	Universal (Should have provisions to attach/ remove clamps for conical flasks and holds assortment of various size of flask range from 250 ml to 2 Ltrs.)
3.11	Platform MOC	Corrision resisitant stainless steel & should match with cGMP
3.12	Maximum capacity	2 Ltrs. X 6 No of Conical flask to accomdate
3.14	Shelves	Adjustable height shelf for static incubation and storage purpose
3.15	Timer	From 1 to 99.9 Hrs.
3.16	Alarm	Audible and visible alarm should indicate whenever there is a deviation from the set parameter
3.17	Programmability	Minimum 5 programme and should have power failure restart mode (The shaker should restart in the last set temperature and RPM after power failure).
3.18	Type of shaking	Orbital

3.19	Data Communication	USB port (For tranfer of operating data/history.)
3.2	Operating Log Manage	LAN :Factory Option PC and optional himac Log Manager Supporting GLP/GMP
3.21	Illumination	illumination start automatically only after door opening.
3.22	Data Communication	USB port (For tranfer of operating data/history.)
3.23	Electrical Supply	100 to 240 V, 50 to 60 Hz
3.24	Dimension, (W X D X H)	Vendor to specify
3.25	Weight	Vendor to specify
3.26	Quantity	1 Nos.
3.27	**Additonal Requirements**	
3.28	Temperature	a) In built temperature sensors for monitoring the tempaerature. b) The system should have facility to calibrate the temperature and speed via keypad.
3.29	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. b)Samples can be viewed on from the front panel. c) Menu and settings with customizable security levels using password should be provided. d) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. e) Door switch to cut-off shaking motion when put in and out sample. f) User selectable operating modes shall be provided (automatic and mannual)
4	**Material of Construction**	
4.1	Body frame	cGMP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification	
5.2	Chamber shall be insulated properly to maintain inner environment	
5.3	Proper earthing is necessary.	
5.4	Appropriate closure of all parts	
5.5	Automatic power failure restart	

5.6	Equipment should be easily movable (caster & wheel lock sysstem)
6	**Other requirement**
6.1	Cleaning shall be done manually.
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.
6.3	Vendor to give code numbers for each component.
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.
7	**Accessories required**
7.1	2 Ltr Clamps - 10 Nos.
7.2	1 Ltr Clamps - 10 Nos.
7.3	500 mL Clamps - 20 No.
7.4	250 mL Clamps - 20 Nos.
7.5	Additional tools for maintenance and repair.
8	**Regulatory aspects**
8.1	cGMP compliances.
8.2	CE certification
9	**Safety requirements**
9.1	Always follow appropriate laboratory practices when using this equipment.
9.2	Appropriate closure of all parts.
9.3	On power failure equipment should come in safe condition.
9.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
10.2	IOQ Protocol
10.3	Warranty Letter for 1 year from the date of supply.
10.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site.

10.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of completion.
10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information.
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Thermo Fisher Scientific, Sartorius, Brunswick, Scigenics
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-RSIB 01	MBB (Hep-B)	Seed Lab	B1G006	23m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
13-02-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Roller Culture Apparatus**

Document No.: DS-ROL 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies Bulk Block	B4-ROL 01-04	-	4

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process		31-05-2017
Checked by			
Mr. Tushar Shende	Engineer - Process		31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Rabies Bulk P. NAVIN KUMAR	MANAGER - VIRAL VACCINE		08-06-2017
Project / Engineering department VISHNU S	A.M		16-06-2017
Approved by			
Head of the department Rabies Bulk	SM - JE Vaccine		28-06-2017
Head of the department (QA) R. SUDHI BABU	DQM		28-06-2017
Authorized by			
Project Authority			

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Roller Culture Apparatus	
	Document No.	DS-ROL 01	
	Revision No.	00	

1	**Process requirements**	
1.1	Roller culture apparatus is used for propagation of anchorage dependent cells in roller culture bottles.	
2	**Equipment ID**	
2.1	B4-ROL 01-04	
3	**Technical Specification**	
3.1	cGMP Compliance	Required
3.2	Type	Modular
3.3	Number of Bottle Positions	88
3.4	Number of decks	11
3.5	Distance between decks	Vendor to specify
3.6	Unit Height and Width	Height and Width shall not be more than 2 meters and 1.2 meters respectively
3.7	Roller bottle size	110 to 121 mm diameter diameter and up to 550 mm in length (850 cm^2 to 4250 cm^2)
3.8	Motor type	Brushless DC motor
3.9	Display type	Digital with touch screen type
3.10	Speed range	0.2 – 7 RPM
3.11	Speed accuracy	0.1 RPM
3.12	Operating Temperature	15 to 40°C
3.13	Humidity	80% up to 31°C 50% at 40°C
3.14	Control system	Microprocessor based
3.15	Power supply	240 VAC, 50/60Hz, 20 watts or Vendor to specify
3.16	Quantity	4 Nos.
3.17	Dimensions (W x D x H)	Vendor to specify
4	**Material of Construction**	
4.1	Body	Mild SS coated with epoxy
4.2	Wheels	High grade rubber
4.3	Key Pad	PVC
4.4	Frame-modular construction	Rust proof steel; powder coated
4.5	Roller	Rubberized metal tube, chemical resistant rubber
4.6	All bolts and nuts should be with dome caps	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Roller Culture Apparatus	
	Document No.: DS-ROL 01	
	Revision No.: 00	

5	**Specific Equipment requirement**
5.1	The roller culture apparatus should be compatible to hold and operate 850 cm^2 to 4250 cm^2 roller culture bottles
5.2	The system should consist of drive unit mounted on top to provide easy access for maintenance and better air flow with battery backup.
5.3	The roller culture apparatus should have built-in monitoring and alarms in case power failure, belt damage.
5.4	The unit should continuously monitor both the rotational speed and the drive train (the motor and belts).
5.5	Non-slip belt and pulleys for positive traction should be provided.
5.6	The unit should continually display the set RPM and actual RPM during operation
5.7	The unit should be settable to rotate in clockwise and anticlockwise direction as required.
5.8	The unit should be equipped with antistatic lockable wheels with brakes
5.9	**Battery backup system.** a) it should run the full capacity of roller culture bottles at set rpm during power outage. b) It should provide a minimum of 24 hours of auxiliary power.
5.10	**Rotation Alarm System** a) It should monitor drive system. b) Alarm sound if the speed falls out of the entered tolerance or if the unit detects a loss of rotation. c) Alarm should be visual (flashing LEDs), & audible (loud buzzer), .
6	**Other requirement**
6.1	Cleanability of roller apparatus should be possible with standard cleaning agents and disinfectants
6.2	Training on operation and maintenance of the equipment should be provided to the users.
7	**Regulatory aspects**
7.1	NA
8	**Safety requirements**
8.1	On power failure equipment should shift over to battery power.
8.2	On exhaustion of battery audio alarm and should go to safe mode.
9	**Documents**
	Following documents, but not limited to these, should be supplied by the vendor as part of the supply package in hard copy as well as editable electronic file
9.1	Operation and maintenance manuals.
9.2	Vendor should provide warranty for Minimum two years from the date of supply.
9.3	Vendor should provide list of standard spare parts with ordering information.
9.4	Vendor should provide list of change parts (if applicable) with ordering information
9.5	IQ and OQ documents
10	**Timelines**
10.1	Not Applicable

11	Preferred List of Makes
11.1	Bellco, Labmate, Wheaton

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-ROL 01-04	Rabies Bulk Block	-	-	-	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
31-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Shaker Incubator**

Document No.: DS-SIB 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB - Hib	F2-SIB 01	200 L	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Syed Sharique Ahmad	Process Engineer	for Sandip	30-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for T.S. Shukla	30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		30-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM	A K Thakur	07-06-2017
Project / Engineering department VISHNU. S	AM	S. Vishnu	19.06.2017
Approved by			
Head of the department: MBB Dr. Subramanyam V. Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA) Dr. Sumit Bose	DGM	Dr. Sumit Bose	23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Shaker Incubator	
	Project #: 120310	
	Document #: DS-SIB 01	

1	**Process requirements**	
1.1	A shaker incubator is a laboratory instrument used to agiate a biological samples (Microbial culture) by shaking while maintaining optimal environmental conditions.	
2	**Equipment ID**	
2.1	DS-SIB 01	
3	**Technical Specification**	
3.1	Model	Floor Mounted/Table top with static shelves cGMP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Display	LCD, Large easy to read display clearly indicates speed, running time, alarm condition and temperature character.
3.4	Tempaerature Range	Ambient +5 °C to 60 °C and should CFC/HCFC free (cGMP compliant).
3.5	Temperature Resolution	0.1 °C
3.6	Temperature Uniformity	0.2 °C
3.7	Temperature Control Accuracy	± 1°C of set temperature
3.8	Shaking Range	25 to 300 RPM
3.9	Shaking accuracy	± 20 rpm
3.10	Shaking Platform	Universal (Should have provisions to attach/ remove clamps for conical flasks and holds assortment of various size of flask range from 250 ml to 2 Ltrs.)
3.11	Platform MOC	Corrision resisitant stainless steel & should match with cGMP
3.12	Maximum capacity	2 Ltrs. X 6 No of Conical flask to accomdate
3.13	Shelves	Adjustable height shelf for static incubation and storage purpose
3.14	Timer	From 1 to 99.9 Hrs.
3.15	Alarm	Audible and visible alarm should indicate whenever there is a deviation from the set parameter
3.16	Programmability	Minimum 5 programme and should have power failure restart mode (The shaker should restart in the last set
3.17	Type of shaking	Orbital
3.18	Data Communication	USB port (For tranfer of operating data/history.)
3.19	Operating Log Management	LAN ;Factory Option PC and optional himac Log Manager Supporting GLP/GMP
3.20	Illumination	illumination start automatically only after door opening.
3.21	Data Communication	USB port (For tranfer of operating data/history.)
3.22	Electrical Supply	100 to 240 V, 50 to 60 Hz
3.23	Dimension, (W X D X H)	Vendor to specify

3.24	Weight	Vendor to specify
3.25	Quantity	1 Nos.
3.26	**Additonal Requirements**	
3.27	Temperature	a) In built temperature sensors for monitoring the tempaerature. b) The system should have facility to calibrate the temperature and speed via keypad.
3.28	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. b)Samples can be viewed on from the front panel. c) Menu and settings with customizable security levels using password should be provided. d) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. e) Door switch to cut-off shaking motion when put in and out sample. f) User selectable operating modes shall be provided (automatic and mannual)
4	**Material of Construction**	
4.1	Body frame	cGMP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification	
5.2	Chamber shall be insulated properly to maintain inner environment	
5.3	Proper earthing is necessary.	
5.4	Appropriate closure of all parts	
5.5	Automatic power failure restart	
5.6	Equipment should be easily movable (caster & wheel lock sysstem)	
6	**Other requirement**	
6.1	Cleaning shall be done manually.	
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.	
6.3	Vendor to give code numbers for each component.	
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
7	**Accessories required**	
7.1	2 Ltr Clamps - 10 Nos.	
7.2	1 Ltr Clamps - 10 Nos.	
7.3	500 mL Clamps - 10 No.	
7.4	250 mL Clamps - 10 Nos.	

7.5	Additional tools for maintenance and repair.
8	**Regulatory aspects**
8.1	cGMP compliances.
8.2	CE certification
9	**Safety requirements**
9.1	Always follow appropriate laboratory practices when using this equipment.
9.2	Appropriate closure of all parts.
9.3	On power failure equipment should come in safe condition.
9.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
10.2	IOQ Protocol.
10.3	Warranty Letter for 1 year from the date of supply.
10.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site.
10.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of completion.
10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information.
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Thermo Fisher Scientific, Sartorius, Brunswick, Scigenics
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm^2 (Area)	Room height in mm
DS-SIB 01	MBB (Hib)	Seed preparation room	B1G109	18000 mm^2	NA

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Shaker Incubator	
	Project #: 120310	
	Document #: DS-SIB 01	

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment	

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: UV- Visible Spectrophotometer

Document No.: DS-SPM 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB - Hep B	B1-SPM 01	-	1
B1	MBB- Hib	B1-SPM 02,03	-	2

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	31-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	for. T.S.Shiva	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB CH. RAJESH	DM		08-06-2017
Project / Engineering department VISHNU.S	AM		16-06-2017
Approved by			
Head of the department: Rabies Bulk M.V. Subrahmanyam MBB	Head Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA)	QAM		29-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	UV- Visible Spectrophotometer	
	Document No.	DS-SPM 02	
	Revision No.	00	

1	**Process requirements**	
1.1	UV-visible spectrophotometer is used for the measurement of transmittance or reflectance absorbed by a sample at a given wavelength.	
2	**Equipment ID**	
2.1	B1-SPM 02	
3	**Technical Specification**	
3.1	Model	cGMP complaint
3.2	Type	UV visible spectrophotometer
3.3	Spectrum Band Width	1nm
3.4	Wavelength Range	190 - 1100 nm
3.5	Wavelength accuracy	±0.1 nm at 656.1 nm D2
		±0.3 nm (190 - 1100 nm)
3.6	Lamp sources	Xenon flash lamp/tungsten/halogen lamp/deuterium lamp built in light source auto position adjustment with life of average 3000 hours
3.7	Lamp interchange wavelength	Automatic interchange linked to wavelength
3.8	Wavelength length display	0.1 nm increments
3.90	Wavelength slew rate	about 6000nm per minute
3.10	Wavelength length scanning speed	2nm to 3000nm per minute
3.12	Wavelength reproductivity	lesser than ± 0.02nm
3.12	stray light	Less than 0.02% NaI at 220 nm, $NaNO_2$ at 340 nm, less than 1.0% KCl at 198 nm.
3.13	Photometric system	Double Beam
3.14	Photometric measurement modes	Absorbance, transmittance, Concentration
3.16	Photometric ranges	Absorbance -4 to 4 Abs.
		Transmittance 0% to 400%
		Concentration ± 9999.

3.17	Photometric Accuracy	< ±0.005 Abs at 440.0,465.0,546.1,590.0 and 635.1 nm,1 Abs (NIST 930e), <±0.01 Abs at 235,257,313,350,430 nm (Potassium dichromate, EP method)
3.18	Photometric repeatability	< ±0.001 Abs at 0.5 Abs, < ±0.001 Abs at 1.0 Abs,< ±0.003 Abs at 2 Abs.
3.19	Photometric noise	<0.00005 Abs(700 nm)
3.20	Photometric stability	<0.001 Abs/hr. at 0Abs, 340nm after one hour warm up. Measured over 1 hr. Every 5 seconds constant ambient temp
3.21	Base line stability	<0.0003 Abs/hr (700nm, 1 hr after light source turned on).
3.22	Base line flatness	<0.001 Abs 0.5 seconds blank, 0.5 seconds rms.
3.23	Software	Vendor to be specify.
3.24	Weight	Vendor to specify.
3.25	Dimension	Vendor to specify.
3.26	PC Requirement	Suitable PC to be provided by the vendor
3.27	Power requirement	To be compatible to standard Indian Power supply socket.
3.28	Quantity	3 Nos.
4	**Material of Construction**	
4.1	Body	cGMP complaints
4.2	Cuvettes	For Measurements in UV range: Quartz cuvettes standard size and 1ml size. For Measurements in the visible range: Glass standard size ad 1 ml size
4.3	Detector	Silicon photodiode
5	**Specific Equipment Requirements**	
5.1	It should display the Process curve section, data.	
5.2	Open sample area for convenient sample handling.	
5.3	Fast spectral scanning for complete spectral information and multi wavelength applications.	
5.4	Own clock for time and date stamps of the spectra.	
5.5	Extensive self-test procedures that check the electronics and key optical to ensure consistent performance between validations.	
5.6	Display panel shall be supported to graphical representation with LCD back light and keypad shall be sealed membrane with tactile response keys.	
5.7	USB data port should be provided to transfer the data. Connectivity USB port type A for USB Stick.USB port type B for Computer, USB port type A for printer.	

5.8	Data should be able to be printed with the help of printer.	
5.9	It should give automatic calculation of dilution factors.	
5.10	Equipment shall be compatible for cleaning with all standard disfectants.	
6	**PC & printer Requirements**	
6.1	Type	Vendor to specify
6.2	HDD	Vendor to specify
6.3	Operating System	Vendor to specify
6.4	CPU	Vendor to specify
6.5	Video	Vendor to specify
6.6	RAM	Vendor to specify
7	**Other Requirements**	
7.1	Main power ON/OFF switch on control panel	
7.2	Training/Demo for the users on operation and cleaning to be provided.	
8	**Regulatory aspects**	
	The equipment shall be as per GLP or GMP standards.	
7.1	CE certification	
9	**Safety requirements**	
	Following facilities must be provided to protect personnel and equipment:	
9.1	Appropriate closure of all parts.	
9.2	Proper earthing is necessary.	
10	**Documents**	
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.**	
10.2	IOQ documents.	
10.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.	
10.4	List of standard spare parts with ordering information.	
10.5	Warranty letter for 1 year from the date of supply.	
10.6	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.	
11	**Timelines**	
11.1	Not Applicable	
12	**Preferred list of Makes**	
12.1	Shimadzu, Perkin Elmer, Agilent, Thermo Scientific	

Equipment Specification Data Sheet						
HLL Biotech Limited, Chennai						
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU					HBL
	Equipment Name	UV- Visible Spectrophotometer				
	Document No.	DS-SPM 02				
	Revision No.	00				
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.					

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-SPM 01	MBB - HepB	IPQC Room	B1G008	11m2	2700
B1-SPM 01	MBB - Hib	IPQC Room	B1G107	8m2	2700
B1-SPM 02,03	MBB - Hib	IPQC Room	B1G135	9m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Table Top Centrifuge**

Document No.: DS-TTC 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
~~F2-~~ B1	Hepatitis B Block	F2-TTC 01	1 ml tubes	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Syed Sharique Ahmad	Process Engineer	Sharique	24-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	For T.S.Shukla	24-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		24-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: ~~BVF~~ MBB	DM		07-06-2017
Project / Engineering department VISHNU.J	AM		20-06-2017
Approved by			
Head of the department: BVF	DGM		07-06-2017
Head of the department (QA)	DGM		07-06-2017
Authorized by			
~~Project Authority~~	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Table Top Centrifuge	
	Project #	120310	
	Document #	DS-TTC 01	

1	**Process requirements**	
1.1	A table top centrifuge can be used to determine the wet mass of the fermentation culture for IPQC testing purpose .	
2	**Equipment ID**	
2.1	F2-TTC 01	
3	**Technical Specification**	
3.1	Model	cGLP compliant (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Display	Colour TFT
3.4	Determination Tempaerature Range	Ambient +2 °C to 40 °C
3.5	Operating Tempaerature	0 °C to 40 °C, non condensing
3.6	Speed	it should have option accelaration and decelerate speed at the various options.
3.7	Rotor	fixed angle rotor
3.8	Noise level	noise level should be less than 60db when measuring from one meter from equipment
3.9	g force	approximatly 23000
3.10	Temperature Resolution	0.1 °C
3.11	No.of samples	minimum 12 samples and 1.5/2 ml tube size
3.12	Dimension, (W X D X H)	Vendor to specify
3.13	Weight	Vendor to specify
3.14	Quantity	1 nos.
4	**Material of Construction**	
4.1	Body frame	cGLP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification	
5.2	Chamber shall be insulated properly to maintain inner environment	

5.3	Proper earthing is necessary.
5.4	Appropriate closure of all parts.
6	**Other requirement**
6.1	Cleaning shall be done manually.
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.
6.3	Vendor to give code numbers for each component
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.
7	**Accessories required**
7.1	vender should be provided 1000 No. of 1.5 ml centrifuge tubes.
8	**Regulatory aspects**
8.1	cGLP compliances.
8.2	CE certification
9	**Safety requirements**
9.1	Always follow appropriate laboratory practices when using this equipment.
9.2	Appropriate closure of all parts.
9.3	On power failure equipment should come in fail safe condition and must retain the data.
9.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment.
10	**Documents**
10.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
10.2	IOQ Protocol.
10.3	Warranty Letter for 1 year from the date of supply.
10.4	Operation and maintenance manuals shall be provided.
10.5	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
10.6	All equipment warranty should be valid for one year from the date of completion.

10.7	Vendor should provide list of standard spare parts with ordering information.
10.8	Vendor should provide list of change parts (if applicable) with ordering information
11	**Timelines**
11.1	Not Applicable
12	**Preferred list of Makes**
12.1	Thermo fisher,eppendorf.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F2-TTC 01	Hep-B block	IPQC	B1G008	11m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Syed Sharique Ahmad	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Digital Thermo Hygrometer

Document No.: DS-DTH 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F4	BCG	F4-DTH 02-29	-	28

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Tushar Shende	Process Engineer		31-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for Sandeep	31-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		31-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: BCG Bulk Bhuvaneswari	AM		08-06-2017
Project / Engineering department VISHNU.S	AM		16-06-2017
Approved by			
Head of the department: BCG Bulk Dr. Subramanyam V. Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA) Dr. Suresh Babu	DGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited Chennnai			
nne	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment name	Digital Thermo-Hygro Meter	
	Project #	120310	
	Document #	DS-DTH 02	

1	**Process requirement**	
1.1	The equipment is used to monitor temperature and relative humidity	
2	**Equipment ID**	
2.1	F4-DTH 02-29	
3	**Technical Specification**	
3.1	Range	RH: 30to 80% and above
3.2	Accuracy	RH:±5%;Temerature:±0.8°C
3.3	Display	Dual LCD display
3.4	Temperature limits	0 to 60°C
3.5	Resolution	Relative humidity: 1% Temp:0.1°C
3.6	Power requirements	As per vendor specification.
3.7	Battery life	Vendor to specify
3.8	Weight	not more than 200 gms
3.9	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.10	Quantity	28
4	**Material of Construction**	
4.1	Outer Body	As per vendor specification.
5	**Specific Equipment requirment**	
5.1	The temperature hygrometer should have dual display for temperature and humidity	
5.2	Monitor the temperature in °C/ °F and humidity.	
5.3	It should have portable	
5.4	The thermo hygrometer should be quick responsibal to temperature and humidity	
5.5	Display back-light shall be require	
5.6	Should have the internal memory to store 100 readings.	
6	**Other requirement**	
6.1	Training/demonstration to be provided to users.	
6.2	The equipment should be easy to use and clean.	
6.3	All bolts,nuts on the exterior part of equipment should be with cap head or cap nut	
6.4	There should be no crevices,so as to avoid dust accumulation.	
7	**Regulatory guidelines / standrds**	
7.1	The equipment shall be as per cGLP standards	
8	**Safety requirements**	
8.1	No sharp edges/Corners, crevices in the equipment.	
8.2	Appropriate closure of all parts	
9	**Documents**	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:	
9.1	IQ/OQ/PQ validation documentation/onsight activation	
9.2	Operation and maintenance manuals	

Equipment Specification Data Sheet		
HLL Biotech Limited Chennnai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL
	Equipment name: Digital Thermo-Hygro Meter	
	Project #: 120310	
	Document #: DS-DTH 02	

9.3	Calibration certificate should be provided
9.4	One year Warranty letter. from the date of supply
9.5	List of standard spare parts with ordering information.
9.6	Onsite calibration / other terms of calibration
9.7	Training for the technical persons to be included to handle the equipment.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Dwyer, Mextech, Kusam
11.2	**NOTE:** Accurate size and technical specification need to be mentioned by the vendor

Table-1:

Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
F4-DTH 02-29	BCG	NA	NA	NA	NA

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Tushar Shende	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Ultrasonic Bath**

Document No.: DS-USB 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F2	BVF	F2-USB 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Tushar Shende	Process Engineer		23-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for Sandip	23-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		23-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: BVF CH. LAKSHMI PUNNARAO	Manager		05-06-2017
Project / Engineering department VISHNU. S	A.M		21-06-2017
Approved by			
Head of the department: BVF	DGM		05-06-2017
Head of the department (QA)			05-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited Chennnai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment name: Ultrasonic Bath	
	Project #: 120310	
	Document #: DS-USB 02	

1	**Process requirement**	
1.1	Ultrasonic bath is used for filter cleaning and HPLC mobile phase degassing.	
2	**Equipment ID**	
2.1	F2-USB 02	
3	**Technical Specification**	
3.1	Model	Vendor to specify
3.2	Display	LCD/LED
3.3	Time Range	Vendor to specify
3.4	Temperature Range	Ambient to 65 °C
3.5	Bath Capacity	10L or near to its standard
3.6	Ultrasonic frequency	35 to 45 kHz
3.7	Degas/Autogas	Required
3.8	Drain Duct	Required
3.9	Power required	To be compatible with standard Indian power supply socket
3.10	Quantity	1 no.
4	**Material of Construction**	
4.1	Body	Vendor to specify
4.2	Inner Chamber	Stainless steel
5	**Specific Equipment requirment**	
5.1	Settable Operating temperature and Time	
5.2	Equipment shall be compatible for cleaning with all standard disinfectants	
6	**Other requirement**	
6.1	Wire Basket (MOC: Stainless steel) to be provided.	
6.2	Training/Demo for the users on operation and cleaning to be provided.	
7	**Regulatory guidelines / standrds**	
7.1	The equipment shall be as per cGLP standards	
8	**Safety requirements**	
8.1	No sharp edges/Corners, crevices in the equipment.	
8.2	Appropriate closure of all parts	
9	**Documents**	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:	
9.1	IQ/OQ/PQ validation documentation/onsight activation	
9.2	Operation and maintenance manuals	
9.3	Calibration certificate should be provided	
9.4	One year Warranty letter.	

9.5	List of standard spare parts with ordering information.
9.6	Onsite calibration / other terms of calibration
9.7	Training for the technical persons to be included to handle the equipment.
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Grant, Elma Sonic P, Cole parmer
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1:

Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
F2-USB 02	BVF	Preparation Room	F2009	6800 x 4300	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Tushar Shende	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Vacuum Pump**

Document No.: DS-VAP 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	MBB-HiB	DS-VAP 02	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Syed Sharique Ahmad	Process Engineer	Sharique	30-05-2017
Checked by			
Mr. Yogesha M J	Process Engineer	for T.S.Shukla	30-05-2017
Approved by			
Mr. Krishna Amrutam	Manager- Formulation, Fill & Finish		30-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		16.06.2017
Project / Engineering department VISHNU. S	AM		16.06.2017
Approved by			
Head of the department: MBB Dr. Subrahmanyam V. Manthra	Head Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department (QA)	AGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Vacuum Pump	
	Project #	120310	
	Document #	DS-VAP 02	

1	**Process requirements**	
1.1	Vacuum pump is used for degassing and filtration of aqueous solutions.	
2	**Equipment ID**	
2.1	B1- VAP 02	
3	**Technical Specification**	
3.1	Model	cGMP, Vendor to specify
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Noise Level	50 dB
3.4	Max Flow rate	Vendor to specify
3.5	Max Vacuum	min 61 cm (24 Hg)
3.6	Type	Diaphragm headed, Oil free Vacuum Pump
3.7	Motor Type	Permanent split capacitor
3.8	Free-air capacity	1 CFM (client to confirm)
3.9	Pump	Built in Motor mounted
3.10	Maximum Pressure	65 psig
3.11	Maximum Tempaerature	Vendor to specify
3.12	Dimension, (W X D X H)	Vendor to specify
3.13	Weight	Vendor to specify
3.14	Quantity	1 No.
4	**Material of Construction**	
4.1	Body frame	cGLP Compliance
4.2	Wetted Parts	SS
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification	
5.2	Chamber shall be insulated properly to maintain inner environment	

5.3	Proper earthing is necessary.
5.4	Appropriate closure of all parts
6	**Other requirement**
6.1	Cleaning shall be done manually.
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.
6.3	Vendor to give code numbers for each component
6.5	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants
6.6	Vacuum Gauge
6.7	Pressure Gauge
6.8	Flexible Coupling
6.9	Automatic drain valve
7	**Regulatory aspects**
7.1	cGLP compliances. Calibration certificate for pressure guage
7.2	CE certification
8	**Safety requirements**
8.1	Always follow appropriate laboratory practices when using this equipment.
8.2	Position and operate equipment in dry, clean and non combustible work surface.
8.3	Do not allow the power cord to contact hot surfaces of the equipment accessories or sample.
8.4	If spillage occurs, immediately disconnect the power supply to prevent fire hazard
9	**Documents**
9.1	**Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file**
9.2	IOQ Protocol.
9.3	Warranty Letter for 1 year from the date of supply.
9.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site

9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.6	All equipment warranty should be valid for one year from the date of completion.
9.7	Vendor should provide list of standard spare parts with ordering information.
9.8	Vendor should provide list of change parts (if applicable) with ordering information
10	**Timelines**
11.1	Not Applicable
11	**Preferred list of Makes**
11.1	Thermofisher, Cole Parmer,PALL
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-VAP 02	MBB-HiB	IPQC	BIG107	8m2	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
16-01-2017	Syed Sharique Ahmad	00	-	New document

Table-3: Annexure

Not applicable

nne

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Potentiometer**

Document No.: DS-POT 01 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-POT 01	-	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	29-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	for T.S.Shukla	29-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		29-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: Quality Control	DM		07-06-2017
Project / Engineering department VISHNU.S	AM		20.06.2017
Approved by			
Head of the department Quality Control	SM		21-06-2017
Head of the department (QA)			22-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Potentiometer	
	Document No.: DS-POT 01	
	Revision No.: 00	

1	**Process Requirements**	
1.1	Potentiometer is used in titrations like aqueous,non aqueous and potentiometric titrations.	
2	**Equipment ID**	
2.1	Q1-POT 01	
3	**Technical Specifications**	
3.1	Model	cGLP Model
3.2	Type	Integreted dosing unit with 3 exchange units
3.3	Burette Resolution	1:20000
3.4	Sensor pH Resolution	0.001
3.5	Sensor mV Resolution	0.1
3.6	Sensor Temparature resolution	0.1° C
3.8	Temparature sensor	Pt1000
3.9	Titration	Should support aqueous,non aqueous and precipitation titrations
3.10	DET,MET,SET	Should present
3.11	Burette Volume	10ml
3.12	Number of Burettes	3 Nos
3.13	Titration	Able to support parllel titration
3.14	KF provison	optinol
3.15	Electrodes	pH Electrode,Non aqueous elctrode,Silver ring elctrode.
3.16	Filling and dispensing s	30 sec or better
3.17	Interface	USB
3.18	Software	A Single software complaint with data(Spectra) library of standards
3.17	Power supply	240 VAC, 50/60 Hz
3.18	Quantity	1 No
3.19	Dimensions (W x D x H) Internal Work area External dimensions	Vendor to specify
4	**Material of Construction**	
4.1	Body	Epoxy powder coated corrsion resistant
4.2	Finishes	Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Potentiometer	
	Document No.: DS-POT 01	
	Revision No.: 00	

5	**Specific Equipment Requirements**
5.1	Comptable PC should be provided
5.2	Automatic recognition of exchange units and sensors are provided to recognise the electrodes automatically.
5.3	MEANS.STAT,CAL parameters should compatable.
5.4	Store calibration data,analysis data in electrodes.
5.5	Password security should be provided for data.
5.6	convert analog signal to digital signals with out any floucation and interuptions.
5.7	Extensive diagnostics, error detection and display machanisam should be present
6	**Other Requirements**
6.1	Accessories required : Magnetic stirrer,base palte,clamping ring,support road,elctrode holder,Glass bottles , elctrodes of aqueous,non aqueous,silver ring electrode and appropriate electrode storage buffers
6.2	It shall have capacity to save the data for 100 measurments.
6.3	2 USB port shall be provided for acess
6.4	LED display shall be provided for process monitoring and alarm indicator.
6.5	Download the Data to your computer or printer
7	**Regulatory guidelines / standards**
7.1	The equipment shall be as per cGMP standards,
7.2	All measurements are made automatically, which eliminates the need for operator judgment.
7.3	Calibration with fluids traceable to NIST and calibration data securely stored and available for review.
7.4	Operator Traceability, full 21 CFR Part 11 compliant password system
7.5	Verification step with electronic signature.
8	**Safety Requirements**
8.1	Appropriate closure of all parts.
8.2	CE Certification and Proper earthing should be given for the instrument.
8.3	Adjustable down stopper to prevent accidental damage to slides
9	**Documents**
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.
9.2	Operation and maintenance manuals, with trouble shooting tips (Both soft and Hard copies) and IQ,OQ Documents.
9.3	One year Warranty.
9.4	List of standard spare parts with ordering information.
9.5	Calibration and inspection certificates.
9.6	Training for the technical persons to be included to handle the equipment., Compliance and calibration certificates, instrumentation and control wiring drawings, complete IQ,OQ,PQ documents for hardware (soft and hard copies), accessories and spare parts list, procedures for calibration and cleaning etc.

10	Timelines
10.1	Not Applicable
11	Preferred list of Makes
11.1	Metrohm,Mettler Toledo
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-POT 01	Admin, QA & QC	Instrumentation Lab	Q1S020	6440X3465	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Water Bath**

Document No.: DS-WBH 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B1	HiB	B1-WBH 02-04	20 L	2 1
R1	Measles	R1-WBH 02-03	30L	2
Q1F	Mycoplasma Lab	Q1F WBH 02	20L	1

NNE Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	25-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	For T.S. Shenoy	25-05-2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		25-05-2017

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department: MBB Anoop Kumar	AM		06-06-2017
User department: MR Kuldip Mane	AM		06-06-2017
User department: Quality Control V. CHITRA PRIYA	DM		06-06-2017
Project / Engineering department VISHNU. S	AM		20-06-2017
Approved by			
Head of the department MBB V. Mantra	Head - Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department MR Dr. R. KUMARAN	DVP		22-06-2017
Head of the department Quality Control	DGM		22-06-2017
Head of the department (QA) Dr. SURESH BABU	DGM		22-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED
	Equipment Name	Water bath		
	Document No.	DS-WBH 02		
	Revision No.	00		

1	Process Requirements			
1.1	The Water bath shall be used for the incubation of various samples under controlled temperature			
2	**Equipment ID**	**Capacity (L)**	**Type**	**Pump capacity flow rate (Liter per minute)**
2.1	B1-WBH 02-03	20 L	Stationary	NA
2.2	Q1F-WBH 02	20L	Stationary	NA
2.3	R1-WBH 02-03	30L	Stationary	NA
2.4	B1-WBH 04	20L	~~Ciculatory~~ Stationary	NA

3	Technical Specifications	
3.1	Model	cGMP model
3.2	Heating capacity(kW)	Vendor to specify
3.3	Inner chamber size (LxWxH)	Vendor to specify
3.4	External dimension(LxWxH)	Vendor to specify
3.5	Temperature controlling mecahnism	Microprocessor based PID temperature controller
3.6	Expected operational hours per day	24 hrs
3.7	Display	LED display for temperature
3.8	Working temperature range	Ambient temperature +5°C to 100°C
3.9	Temperature stability	±0.2 °C
3.10	Temperature Uniformity	±0.1 °C
3.11	Resolution	±0.1 °C
3.12	Temperature selection	Digital Microprocessor controller (soft touch)
3.13	Quantity	5No's (~~Circulatory - 1No~~, Stationary - 4 Nos)
3.14	Power requirement	To be compatible to standard Indian Power supply socket

4	Material of Construction	
4.1	Inner chamber	SS 304 mirror finish
4.2	Exterior chamber	cGMP compliant exterior
4.3	Heating element	Stainless Steel

4.4	Lid or top cover	cGMP compliant material preferably transparent
4.5	Perforated tray	Stailess Steel
4.6	Racks for test tubes	Stainless Steel
5	**Specific Equipment Requirements**	
5.1	Should be cGMP Compliant	
5.2	Seamless,splash proof key pad with characteristic symbols should be provided for easy operation.	
5.3	Audible and optical alarms are required for protecting from dry-running condition.	
5.4	Warning measures (audio visual alarm) for deviation of temperature to ± 0.5 °C from set point	
5.5	Drain should be provided for the ease of emptying the bath.	
5.6	All parts in contact with water should be made of SS304	
5.7	Minimum and Maximum Fill level should be clearly indicated by a marking on the inner surface of the bath.	
5.8	The lid should be designed in such a way that the dropping back of the condensate into the test tubes/containers should be avoided.	
5.9	The water bath outer surface should not have any sharp corners.	
5.10	The equipment shall be compatible for cleaning with all standard disinfectants.	
6	**Other Requirements**	
6.1	The equipment must be portable	
6.2	Training/Demo for the users on operation and cleaning be provided.	
7	**Regulatory Aspects**	
7.1	CE certificate.	
8	**Safety Requirements**	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all parts.	
8.2	Proper earthing is necessary.	
8.3	Water bath should be insulated to avoid dissipation of heat to external surface	
9	**Documents**	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file	
9.1	IOQ documents	
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at the site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
10	**Timelines**	
10.1	Not Applicable	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Water bath	
	Document No.: DS-WBH 02	
	Revision No.: 00	

11	Preferred list of Makes
11.1	JEIOTEK,JULABO,VELP
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-WBH 04	HiB	Conjugation & Purification	B1G133	43m2	2700
Q1F-WBH 02	Mycoplasma Lab	Instrumentation	Q1F009	4700 x 7300	2700
R1-WBH 02	MR	Cell Culture Area	R1G071	3800X4500	2400
R1-WBH 03	MR	Cell Culture Area	R1G093	4830X3650	2400
B1-WBH 02-03	HiB	IPQC	B1G135	9m2	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

nne®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Weighing balance**

Document No.: DS-WBG 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1F	Mycoplasma	Q1F-WGB 01	220 g	1
B1 (HEP)	MBB	B1-Hep-WGB 02,03,04	150 Kg	3
B1 (HEP)	MBB	B1-Hep-WGB 05	15Kg	1
B1 (HEP)	MBB	B1-Hep-WGB 06	820 g	1
B1 (HEP)	MBB	B1-Hep-WGB 07	410 Kg	1
F4	BCG	F4-WGB 01,02,03	1 g-600 g	3
F4	BCG	F4-WGB 04	10g-10 kg	1
R1	Measles	R1-WGB 01	100 mg to 1000 g	1
R1	Measles	R1-WGB 02,03,04,05,06	100 g to 40 kg	5
B1 (HIB)	MBB	B1-WGB 01,02	220g	2
B1 (HIB)	MBB	B1-WGB 03	10 Kg	1
B1 (HIB)	MBB	B1-WGB 04,05,06,07	50 Kg	4
F1	VVF- MR	F1-WGB 02	100 g to 40 kg	1

NNE Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Engineer - Process	Sandeep	26-05-2017
Checked by			
Mr. Yogesha MJ	Engineer - Process	for. T.S. Shetty	26.05.2017
Approved by			
Mr. Krishna Amrutam	Manager - Formulation, Fill & Finish		26.05.2017

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: Quality Control B. Abhilash Choudari	DM	B. Abhilash Choudari	06.06.2017

nne

HBL HILLBIOTECH LIMITED

Equipment Specification Data Sheet | **Equipment Name: Weighing balance**

Document No.: DS-WBG 02 | **Revision: 00**

Project No.: 120310 | **Project Name:** Integrated Vaccines Complex, Chengalpattu

User department: MBB Ch. RAJESH	DM		06.06.2017
User department: BCG Elayavan.	AM		06.06.2017
User department: MR Kuldip Mane	AM		06.06.2017
User department: VVF Kuldip Mane	AM		06.06.2017
Project / Engineering department VISHNU.S	AM	S. Vishnu	20.06.2017
Approved by			
Head of the department Quality Control	DGM		23-06-2017
Head of the department MBB V. Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department BCG V. Mantha	Head-Bacterial Vaccines	M.V. Subrahmanyam	22-06-2017
Head of the department MR Dr. R. KUMARAN	DVP		22-06-2017
Head of the department VVF Dr. R. KUMARAN	DVP		22-06-2017
Head of the department (QA)	DGM		23-06-2017
Authorized by			
Project Authority	NA		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED
	Equipment Name: Weighing balance	
	Document No.: DS-WGB 02	
	Revision No.: 00	

1	Process requirements
1.1	Weighing balances will be used for determining weight or mass of salts and other chemicals, which shall be used in the process and also for specific areas like animal house, they are used for weighing laboratory animals for materials like animal feed,bedding material etc.

2	Equipment ID		
	Equipment ID	Capacity	Quantity
2.1	Q1F-WGB 01	220 g	1
2.2	B1-Hep-WGB 02,03,04	150 Kg	3
2.3	B1-Hep-WGB 05	15Kg	1
2.4	B1-Hep-WGB 06	820 g	1
2.5	B1-Hep-WGB 07	410 Kg	1
2.6	F4-WGB 01,02,03	1 g-600 g	3
2.7	F4-WGB 04	10g-10 kg	1
2.8	R1-WGB 01	100 mg to 1000 g	1
2.9	R1-WGB 02,03,04,05,06	100 g to 40 kg	5
2.1	B1-WGB 01,02	220g	2
2.11	B1-WGB 03	10 Kg	1
2.12	B1-WGB 03	50 Kg	4
2.13	F1-WGB 02	100 g to 40 kg	1

3	Technical Specification	
3.1	Model	cGLP model
3.2	Unit of display	Milligram, Grams , Kilograms
3.3	Linearity	Vendor to specify
3.4	Measuring System	Vendor to specify
3.5	Tare	Full Weighing Range
3.6	Calibration	External, internal calibration is required
3.7	Display	Backlight LCD display
3.8	Operational Temperature	(-5 °C) to 50 °C (system shall be suitable)
3.9	Door	Opening from 2 sides and top sides
3.1	Power Requirement	To be compatible to standard Indian power supply socket
3.11	Quantity	25 Nos.

4	**Material of Construction**	
4.1	MOC of Door	Acrylic (for analytical balances)
4.2	MOC of Pan	SS 304
5	**Specific Equipment requirement**	
5.1	The Balance should be properly levelled. In-build spirit level for level adjustment should be provided	
5.2	Should be easily cleanable and compatible with all standard disinfectants	
5.3	Standard weights should be provided for the calibration (E1 - 21 pieces weigh set - 1 no) with certification and traceability.	
5.4	Auto calibration facility should be provided.	
5.5	Balance should be capable of counting tarring, totalizing,percentage weighing,toggling between gross/net value.	
6	**Other requirement**	
6.1	Display should be Back light LCD/Graphic display.	
6.2	On power failure equipment should come in fail safe condition,Over load, low battery indicator and auto power off should be provided.	
6.3	Enclosure should be removable whenever required. Clean ability of weighing balance by removing the pan should be possible	
6.4	Power failure and recovery should be provided, equipment settings should not get disturbed due to power failure.	
6.5	Printer provision of RS 232 port with weighing balnace shall be considered for printing time and weight data for the sample.	
6.6	Memory function, to keep the last 20 weight in memory.	
6.7	SS ramp should be provided to move the weighing balances.	
6.8	Training/ demo for the users on operations and cleaning to be provided.	
7	**Regulatory aspects**	
7.1	CE certification	
8	**Safety requirements**	
8.1	Appropriate closer of all parts shall be considered	
8.2	Proper earthing is necessary	
9	**Documents**	
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.	
9.2	IOQ Protocol to be provided	
9.3	Comprehensive one year warranty letter from the date of supply.	
9.4	Operation, calibration and maintenance manuals along with IOQ documents during installation at site to be provided.	
9.5	MOC Certificates to be provided by Vendor.	
9.6	Calibration certificate of critical instrumnets with respect to the traceable national reference standard instrument and their calibration procedure to be provided	

10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Shimadzu, Mettler Toledo, Sartorius.
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			HBL HLL BIOTECH LIMITED	
	Equipment Name	Weighing balance			
	Document No.	DS-WGB 02			
	Revision No.	00			
Equipment ID	**Block Name**	**Room Name**	**Room No**	**Room dimension in mm**	**Room height in mm**
Q1F-WGB 01	Mycoplasma	Materila Prep	Q1F014	26m2	2700
B1-Hep-WGB 02,03	MBB-Hep-B	Dispensing room	B1G018	14m^2	2700
B1-Hep-WGB 04	MBB-Hep-B	Sterile filtration	B1G036	25m^2	2700
B1-Hep-WGB 05	MBB-Hep-B	Dispensing room	B1G018	14m^2	2700
B1-Hep-WGB 06	MBB-Hep-B	Chromatography	B1G043	49m^2	2700
B1-Hep-WGB 07	MBB-Hep-B	Dispensing room	B1G018	14m^2	2700
F4-WGB 01	BCG	Harvest and purification	F4G029	49m^2	2700
F4-WGB 02	BCG	Vial filling area	F4G040	111m^2	2700
F4-WGB 03	BCG	Dispensing room	F4G011	11m^2	2700
F4-WGB 04	BCG	Dispensing room	F4G011	11m^2	2700
R1-WGB 01	Measles	Media Preparation Room	R1G042	5400 X 8095	2700
R1-WGB 02,03,04,05,06	Measles	Media preparation	R1G042	5400X8095	2700
B1-WGB 01,03,04	MBB-Hib	Dispensing room	B1G117	14m^2	2700
B1-WGB 02,05	MBB-Hib	Conjugation&Purification	B1G133	43m^2	2700
B1-WGB 06	MBB-Hib	Polysaccharide purification	B1G136	58m^2	2700
B1-WGB 07	MBB-Hib	Sterile filtration	B1G141	32m^2	2700
F1-WGB 02	VVF- MR	Blending & Formulation	F1G080	5410 X 6215	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2017	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable

Installation Requirement Specification and Specific Instructions

Table of Contents

1.0 Approval Signatures

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of HLL BIOTECH LIMITED, and authorized by the appropriate Project Authority.

NNE Pharmaplan India Ltd				
Responsibility	**Name**	**Designation**	**Sign**	**Date**
Prepared By	Mr. Yogesha M J	Technical Assistant (Biotech)		
Reviewed By	Mr. Sridhar Babu K	Asst. Manager – Validation &GMP Compliance		
Approved By	Mr. Vikas Katial	GM –Head COC Vaccines		
HLL Biotech Limited				
Engineering/Projects				
Production				
QC/QA				
COO				

Specifications	Remarks
2.0 Overview	
2.1 Project Introduction	
HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India, is implementing "Integrated Vaccines complex" Chengalpattu. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India. HLL Biotech Limited has associated with NNE Pharmaplan India Limited, hereinafter called as "NP" has been appointed as "Engineering Consultants". NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices. This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian FDA (Schedule M), WHO/GMP regulations.	
2.2 Project Standard	
The facilities, upon completion, shall be in compliance with the Indian FDA (Schedule M), WHO, and also the HBL's internal quality standards.	
2.3 Purpose	
This specification states the mandatory requirements and critical instructions for process systems, process support systems and utility systems.	
3.0 Scope	
3.1 **Systems in scope**	
The specification applies to process systems, process support systems and utility systems used for producing vaccines. For each requirement (see section 5.0 "Requirement specification"), it is more explicitly specified what types of systems the requirements apply to. The specification applies both to new systems and to changes of existing systems (if applicable and then only to the parts that are changed). HVAC systems, automation and electrical building installations are not included in the scope.	
3.2 **Supplementary or changed requirements**	
The specification covers mandatory requirements and critical instructions. There may be cases when more specific requirements than described in this specification are necessary. It may be supplementary requirements; In such cases, the User Requirement Specification (URS) must state which requirements are applicable and where precisely deviations are made from this instruction	
3.3 **Note**	
"**Vendor** is required to adhere to all necessary and applicable requirements. Any specific requirement not applicable should be mentioned in the remark column. Also, any deviation or non-compliance a comment must be inserted or enclosed as a separate	

Specifications	Remarks
annexure by referring to the respective IRS specification number." For more information vendor to refer Tender enquiry document no: NPI-120310-EQP-TD-S1-01.	
4.0 Safety Requirement	
4.1 **General**	
Following facilities must be provided to protect personnel, product and equipment / system:	
4.1.1 In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.	
4.1.2 Noise level <75 db at a distance of 1 meter from the equipment / system.	
4.1.3 Emergency stop switch should be located on accessible areas or within the reach of the operator and a signal has to display when emergency stop button was activated..	
4.1.4 Earthing all parts of the machine, including doors, movable units etc to the earth grid/cable/tag box, supplied by the electrical contractor	
4.1.5 In case of power failure, the system must be protected in the following priority and the likeliness of damages must be minimized: • Persons and environment • Equipment • Product	
4.1.6 For the safety of the operator the external surfaces should not have temperature more than 45℃.	
4.1.7 Warning stickers on all hot surfaces	
4.1.8 Appropriate closure of all rotating parts of machine.	
4.1.9 Appropriate failure detection and alarm notification	
4.1.10 All machine doors which are closed during production, according to operator safety, have to be supervised by security switches. In case of door opening the machine must stop immediately.	
4.1.11 Explosion proof design.	
4.1.12 Motor fault or over load.	
4.1.13 Sufficient lighting inside machine housing and control cabinets must be provided by the vendor.	
4.1.14 Vibrations shall not exceed level acceptable according ISO 10816.	

Specifications		Remarks
4.1.15	All lines and equipment surfaces which represent a danger to operators and maintenance personnel with regard to freezing or burns will be adequately insulated.	
4.1.16	Generally all sensors are supplied via the uninterruptible network. Thus the actual system condition can be displayed even in case of voltage failure.	
4.1.17	Control lights and other display elements shall not be influenced by voltage failure.	
4.1.18	Grounding of the entire framework is required	
4.1.19	All motors have to be thermally protected	
4.1.20	The level of protection of the electrical components has to be IP54 or higher based on the Process requirements.	
4.1.21	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms.	
4.1.22	As per the state electricity board, harmonics for all electrical wiring should remain within 3%. Active or passive filters should be used. The same has to be clearly marked in circuit diagrams. Detailed information to be provided in spare lists etc	
4.2	**Power Failure and Recovery**	
4.2.1	On power failure equipment shall come to rest to protect operator, equipment and the product.	
4.2.2	After power resumption, the machine should not start automatically i.e. human intervention should be required.	
4.2.3	After power regain, the machine should start from the step it stopped with the provision of real time recording and printing facility.	
5.0	**Requirement specification**	
5.1	**Refrence Standard / Guideline for Equipment / System**	

The equipment should comply with the following guidelines / standard:

Sl. No.	Reference Standard / Guideline	Applicability
1.	**Current GMP-Regulations** • EU-GMP-Guideline Part 1, Annexes 1, 11 & 15Schedule “M” GMP • 21 CFR, Part 210 cGMP in Manufacturing, processing, packing or holding of drugs: General • 21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals • WHO Good Manufacturing Practices - Main	General requirement for all the equipments / systems (pharmaceuticals/biologics/vaccines)

Specifications	Remarks

	Principles for Pharmaceuticals Products • WHO Good Manufacturing Practices for biological products **Operating safety act** • The requirements of the Operating safety act must be observed. **ASME-BPE compliance** • ASTM, American Society of Testing Materials • ANSI, American National Standard Institute • AWS, American Welding Society	

Sl. No.	Reference Standard / Guideline	Applicability
2.	**FDA Guidance for Industry** Sterile Drug Products Produced by Aseptic Processing-cGMP	For all equipments/systems used in aseptic manufacturing
3.	**FDA Guidance for Industry** Documentation for Sterilization Process Validation in application for human and veterinary drug products	For equipments used in sterilization such as autoclave / DHS etc
4.	**GAMP** The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 5 **Current GMP-Regulations** 21 CFR Part 11: Electronic Records; Electronic Signatures	For automated / semi – automated computerized systems
5.	**CE Conformity** A CE declaration of conformity must be available. The CE identification must comply with the current EC commission	For products placed on the market in the European Economic Area (EEA) (all the systems / equipments).
6.	**ASME** Section 8- Div I for pressure vessels design ASME-BPE Compliance (As per latest version)	For all pressure vessels / reactors / fermentors / autoclave / sterilizers etc
7.	**ANSI / NSF 49-2008** Biosafety Cabinetry : Design, Construction, Performance and Field Certification	Biosafety cabinet
8.	**ISO 14664** Clean Rooms and its Associated Controlled Environment **(European Standard) EN – 1822 for HEPA**	Any equipments with HEPA filters (RABS / LAF / BSC etc)

Specifications			Remarks
	FILTERS		
9.	**ISO 8362** Injection containers for injectables and accessories	For Vials and closures	

5.2	**Cleaning Requirement**	
5.2.1	Design of equipment should be smooth to enhance cleaning feasibility and by providing zero sharp corners, crevices and smooth weld joints.	
5.2.2	All bolts, nuts on the exterior part of equipment will be with cap head or cap nut	
5.2.3	The vendor shall provide the detail of cleaning agent based on compatibility of material.	
5.2.4	Equipment contact parts shall be easily dismantle-able and cleanable	
5.2.5	The equipment shall be easily accessible for cleaning of non-product contact part at maintenance side of the system	
5.2.6	All gaskets provided to avoid leakage should be able for easy removal & re- fixing.	
5.2.7	The vendor shall provide the detail of utilities requirement for the applicable cleaning (WIP / CIP / SIP).	
5.2.8	Systems with CIP shall be designed for 100% coverage of the internal surface areas.	
5.3	**Qualification Requirement**	
5.3.1	Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) and the performance phase (PQ). Computer system verification as per the standards of GAMP.	
5.3.2	Vendor shall support and provide all necessary documents and test procedures to client for proper execution of all the qualification phases.	
5.4	**Material of Construction (MOC)**	
5.4.1	Materials:	
	Materials: Surfaces in contact with media must be of a material quality which does not react with to, absorb, leach or contaminate the media to an extent that will impact the product quality. The materials specified in row must always be evaluated in relation to the specific media that the material will get in contact with. Particular limitations regarding the use of materials shall be specified in the respective URS.	
	Acid-proof stainless steel, resistance: Many types of acid-proof stainless steel are not	

Specifications	Remarks
sufficiently resistant to media with low pH (under ~3) or high chloride content, particularly HCl solutions. Where acid-proof stainless steel is not sufficiently resistant PP, PE, PVDF or PTFE are recommended.	
Declaration of Compliance: Materials of construction must as a minimum be documented with a Declaration of Compliance from the supplier. The Declaration must contain a guarantee that the used/supplied materials are in compliance with the specified/ordered. Suppliers of pipes, fittings, components, instruments and systems must be able to trace the materials to the material manufacturer's "heat number" and the material composition of the specific batch. The supplier's ability to secure this traceability can for instance be ensured via supervision, audit and performance history as part of the approval of the supplier.	
Specifications:	
• All metallic product contact / critical surfaces should be constructed of SS316 L grade with internal mirror finish (< 0.5µ Ra for filling line and < 0.8µ Ra for lyophiliser) and external surface matte finish (< 1.2µ Ra).	
• All metallic non-product / noncontact / non critical surfaces should be constructed of SS304 grade or better (316 in sterile area) with external surface finish as matte finish (< 1.2µ Ra).	
• Gaskets, seals and O-rings coming in direct / indirect contact surfaces should be constructed of USFDA approved polymeric materials only.	
• Borosilicate glass should be used wherever required eg:- inspection door viewing port in the machine etc.	
• Material of insulation shall be mineral wool/ ceramic wool cladded with SS 304.	
Area of application: The requirements apply to process systems and clean utilities. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests.	

Alternative materials listed below.
• **Acid-proof stainless steel** with content of
  ○ Molybdenum ≥2.0% and Carbon ≤ 0.03%.
• *For example: AISI 316L, AISI 904L, EN1.4404, EN1.4435, EN1.4462,*
• *EN1.4539, UNS S32205, others.*
• Also accepted: AISI 316Ti and EN1.4571.
• If the material is not to be welded, accepted are also:
  ○ Molybdenum ≥ 2.0% and Carbon ≤ 0.08%.
• *For example: AISI 316, EN1.4401, others.*
• **Polymers**, accepted types:
• CSM (Hypalon), E-CTFE, EPDM/EPD, FEP, FFKM, FPM (Viton), PE, PEEK,
• PFA, PP, PTFE (Teflon), PVDF, SI.
• In LPLC columns: acrylic	

Specifications	Remarks
• In addition, the material must comply with 21 CFR part 177 or USP 24 Class VI. • **Liquids** must comply with 21 CFR part 172 or part 178. • *By "liquids in contact with media" is here understood lubricants and other liquids in equipment, components and instruments where there is a high probability of direct contact with the medium by wear and tear, defects, failures, etc.* • **Other materials**, accepted types: ○ Titanium *e.g. EN3.7025, EN3.7035, EN3.7235* ○ Hastelloy *e.g. C4, C22, C276* ○ Ceramics *e.g. alumina, zirconia* ○ Glass*e.g. borosilicate* ○ In mechanical seals and the like, also SiC and WC.	
5.4.2 **Untreated welds**	
Welds: Untreated welds in contact with media must have a sanitary finish. This facilitates easy and effective cleaning and minimise the risk of corrosion, microbial growth and other contamination of the product. For treated (burnished, polished) welds in stainless steel, Plastic welds are not treated.	
100% inspection of all welds is not required. The quality of the welds is instead secured through a number of indirect requirements and spot checks and welder qualification.	
Few welds: In cases when only a few welds are to be carried out, a 100% independent inspection can be chosen instead of the 5% stated in requirement a) In that case, requirements on certificates (b,2) and 20% self-inspection (b,4) are cancelled.	
Self-inspection: By self-inspection is meant an inspection that is carried out by the welding contractor's inspection function.	
Independent inspection: By independent inspection is meant an inspection carried out by a Technical Discipline Specialist who is organisationally independent from the welder. It is recommended to use Technical Discipline Specialists from a organisation with accreditation to perform welding inspections.	
Extended inspection: If the inspection uncovers welding defects or discolorations, the inspection must be extended to determine the extent of the problems (for instance by systematic inspection of the specific welder's work).	
Pickling: For welds in stainless steel there may be cases where it is very difficult to achieve welds without too much discoloration. In such cases, pickling or passivation is acceptable, but it is not recommended as a general procedure.	
Specifications:	
• All welds shall be crack and crevice free.	
• Internal welds and welds likely to be in contact with the product shall be ground smooth and flush. All other welds shall be ground smooth (< 1.2µ Ra).	

Specifications	Remarks
• Clean media pipes shall be orbital welded	
• All welds shall be polished to the same standard as the surrounding areas, with direction of lay following the direction of welding.	
• Insulation material should be non-fibrous and covered with completely welded SS 304 or better cladding.	
• Stainless steel fabrications must be welded under inert gas (Orbital welding) with Boroscopy records and treated by pickling and passivation to pharmaceutically accepted standards, to prevent corrosion.	
Area of application: The requirements apply to process systems. For systems with dry gases there are however no requirement for independent inspection (part of requirement a), and the requirement is verified by commissioning. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests.	
a] Untreated welds in stainless steel in contact with media must be without welding defects – as defined in [ASME BPE, MJ-6] or equivalent standard. Discoloration exceeding ”light straw” or ”light blue” must not exist in the heat-affected zone (cf. [AWS], [Force] or equivalent standard). At least 5% of a system’s welds must be inspected for discoloration and welding defects by an independent Technical Discipline Specialist. The inspection must be targeted the welds that the independent Technical Discipline Specialist considers hardest to make error-free and the inspection must representatively be spread on the welders. The inspection must be carried out using boroscopy, endoscopy or direct visual inspection.	
b] Untreated welds in stainless steel in contact with media must be: 1. Traceable to welder, welding procedure and self-inspection via a welding log. 2. Made by welders holding a valid welding certificate to weld in the specific materials and dimensions. The certificate must be issued by an accredited authority *(for example Force Technology and others)*. 3. Executed according to an approved welding procedure (WPS). 4. Self-inspected by sampling for welding defects and discoloration (cf. req. a). The inspection must be carried out using boroscopy, endoscopy or direct visual inspection. The self-inspection must be carried out on at least 20% of the welds. The inspection must be targeted the welds which the construction supervision staff considers hardest to make error-free and the inspection must be representatively spread on the welders.	
c] Welds in thermoplastics, in contact with media must be 1. Without welding defects - as defined in [ASME BPE, PM-3.4.1] or equivalent standard. 2. Made by fusion welding with a machine where data for critical welding parameters is recorded automatically. 3. ”Beadless butt fusion” type welds in systems with formal requirements to drain ability (see section title "drain-ability).	

Specifications		Remarks
	4. Traceable to welder, welding procedure and welding data via a welding log. 5. Made by welders who hold a valid welding certificate to weld the specific materials. The certificate must be issued by an accredited authority, alternatively an authority approved by the material supplier. 6. Executed according to an approved welding procedure (WPS).	
5.5	**Use of Lubricants**	
5.5.1	Any lubricant, if used in the equipment / system must be of food grade and non-toxic.	
5.5.2	If lubricant use, All lubricating points must be clearly shown and labeled.	
5.6	**21 CFR Part 11 Compliance**	
5.6.1	Automation and Human Machine Interface (HMI); the software/Hardware system should generate data that cannot be manipulated by the operator. Compliance to 21CFR part 11.	
5.6.2	Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software if used to generate, process, store the critical data must be validated and must be upgradeable to 21 CFR Part 11 requirements.	
5.6.3	The vendor may be also allowed to use CAT6 or CAT6a cables,(RJ-45) cables to do communication	
5.6.4	RS 232 interface is required to transfer the data and as well to take the printout.	
5.6.5	A backup of the data must be available on the system, locked and not tampered by the operator. The data must not be able to manipulated by the operator.	
5.6.6	The audit trail for the data integrity may need to include functions such as authorized user, creations, links, embedded comments, deletions, modifications/corrections, authorities, privileges, time and date etc.	
5.6.7	**Area of application:** This requirements apply to all types of critical process equipments and utility systems (such as BMS of HVAC, PW, WFI & PSG) with HMI, PLC / Software	
5.7	**Data Integrity**	
5.7.1	System security shall be provided to access the operation system and to alter configurable parameter values through access password.	
5.7.2	Minimum 3 level password shall be provided as: • **Operator:** Shall provide operator access to allow routine operation of all equipment features • **Supervisor:** Shall provide access to operator level features in addition to critical operating parameter configuration • **System Administrator:** Shall provide the access to the Operator and Supervisor level features in addition to system security parameters.	

Specifications	Remarks
5.7.3 **Area of application:** This requirements apply to all types of critical process equipments and utility systems (such as BMS of HVAC, PW, WFI & PSG) with HMI	
5.8 **Batch Data Display and Record Printing**	
5.8.1 **A complete batch display indicating the following important parameters, but not limited to these:**	
5.8.1.1 Start date and time of operation	
5.8.1.2 End date and time of operation	
5.8.1.3 Product name and Batch No (For process equipments)	
5.8.1.4 All failures alarms (/repeated alarm) and notification	
5.8.1.5 Operator code and name	
5.8.1.6 All process parameters	
5.8.2 **A batch record indicating the following important parameters but not limited to these**	
5.8.2.1 Product name and Batch No (For process equipments)	
5.8.2.2 Start date and time of operation	
5.8.2.3 End date and time of operation	
5.8.2.4 All failures alarms (/repeated alarm) and notification	
5.8.2.5 Operator code and name	
5.8.2.6 Adequate space for writing remarks / corrective actions if any.	
5.8.2.7 Identified space to sign for operator & supervisor.	
5.8.3 **Area of application:** This requirements apply to all types of critical process equipments and utility systems such as PW, WFI & PSG	
5.9 **Desired Documents**	
5.9.1 Vendor must generate all applicable documents during all phases of equipment fabrication i.e. design fabrication, testing and shipment as per applicable standards.	
5.9.2 Following documents, but not limited to these, are expected from the vendor as part of the supply package as hard copy (02 No.) and electronic editable versions in **English** language:	
5.9.3 **Phase 1: Pre-ordering of the equipment**	

Specifications	Remarks
5.9.3.1 Filled in URS	
5.9.3.2 Equipment layout drawing fitted in the room layout block	
5.9.3.3 Detail technical offer that support the compliance of the URS must include the make of the components and P&ID Proposal.	
5.9.4 **Phase 2: Post-ordering and pre-fabrication stage of the equipment**	
5.9.4.1 Functional design specification and technical specification, that should contain the following:	
5.9.4.1.1 Equipment descriptions and its function	
5.9.4.1.2 Equipment operation steps	
5.9.4.1.3 HMI functions with screen shot	
5.9.4.1.4 List of failure indications	
5.9.4.1.5 List of interlocks	
5.9.4.1.6 List of input/outputs and its functions	
5.9.4.1.7 Critical list of major component, devices and instruments with their specific functions, specifications data sheet	
5.9.4.1.8 Schematic/GA drawings of the equipment.	
5.9.4.1.9 List of article contact surface and its MOC	
5.9.4.2 Based on the above documents, equipment design shall be evaluated and approved by the user for the fabrication.	
5.9.5 **Phase 3: Fabrication stage of the equipment & FAT**	
5.9.5.1 Vendor shall provide the Factory Acceptance Test (FAT) protocol at least 4 weeks in advance of the date of FAT, for the approval by the user.	
5.9.5.2 Internal FAT reports compiled by vendor should be shared with the client for reference.	
5.9.5.3 Vendor shall arrange the necessary raw materials (vials, rubber bungs etc) to demonstrate the following tests like productivity, synchronization etc	
5.9.6 **Phase 4: Delivery of the equipment & SAT**	
Delivery of the Equipment:	
5.9.6.1 Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.	

Specifications		Remarks
5.9.6.2	Operation and maintenance manuals, preventive maintenance schedule (with recommended consumables and recommended time interval) for equipment's major component as well as the operating system	
5.9.6.3	Operation and maintenance manuals for the bought out items.	
5.9.6.4	Installation instructions/ guideline for equipment	
5.9.6.5	Final as-built drawing for equipment.	
5.9.6.6	Detailed drawing (plan and minimum one elevation) marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities on the drawing along with the offer.	
5.9.6.7	Other applicable drawings (such as P&ID, electrical, instrumentation etc.)	
5.9.6.8	Spare and/ or change parts list with ordering information	
5.9.6.9	MOC certificates for all direct/ indirect product contact surfaces.	
5.9.6.10	Detailed description of all components with the manufacturer name, code/sr. no., function, MOC, different test reports, manuals with the installation guideline of different components (as applicable) etc.	
5.9.6.11	Equipment, components, valves and instrumentation etc. shall be uniquely identified by some code / numbering system and the same shall be shown in Process & Instrumentation (P&I) and General Arrangement (GA) drawings.	
5.9.6.12	Instrument calibration certificates with respect to the traceable national reference standard instrument and their calibration procedure. Original calibration certificate along with traceability to be submitted by vendor in their IQ file.	
5.9.6.13	Different reports like Welding, Boroscopy, Passivation etc. (whichever is applicable)	
5.9.6.14	Recommended SOPs for operation (Start-up and shutdown), general cleaning and maintenance of each equipment	
5.9.6.15	Guarantee/ warranty certificates for each equipment and major bought-out items, such as PLC, printer, recorders, instrumentation etc.	
5.9.6.16	Software installation CD with 2 back-ups, wherever applicable.	
5.9.6.17	Software recovery procedures in case of computer system breakdown, for equipment control system, wherever applicable.	
5.9.6.18	Vendor must generate and provide all specifications and test certificates of software used in the equipment control and/or monitoring system.	
5.9.6.19	Shipping checklist along with size & gross weight of each equipment	

Specifications	Remarks
5.9.6.20 IQ and OQ protocols	
5.9.6.21 Control System input / output verification data and report (Optional)	
5.9.6.22 Types of Lubricant and Lubrication instructions. Food grade certificate	
Documentation & Drawing Requirement	
5.9.6.23 All documents have to be supplied as Hard copy, PDF and native file (doc, xls, ppt, dwg, etc.).	
5.9.6.24 All documents have to be archived in DIN A4 binders. Larger formats have to be folded according to the requirement.	
5.9.6.25 Each binder must be marked with the binder number and number of binders.	
5.9.6.26 Different documents within a binder must be separated by extra separator sheets	
5.9.6.27 A Table of content is necessary for the whole documentation.	
5.9.6.28 User manual: Descriptions and manuals must contain all necessary information about safety, installation, commissioning, operation, maintenance and troubleshooting.	
5.9.6.29 If an initial calibration will be not carried out, at least a manufacture's calibration certificate must be delivered.	
5.9.6.30 Software back-up copies must be delivered for all used programmes to restore the system or software status quo ante.	
5.9.6.31 The drawing or document number must be clearly identifiable.	
5.9.6.32 Author/date of creation and reviewer/date of review have to be listed on each drawing, plan and diagram.	
5.9.6.33 The scale must be declared.	
5.9.6.34 The size and format of the drawings, plans and diagrams have to be selected in such a way that all information is readable.	
5.9.6.35 All drawings and diagrams must be supplied in AutoCAD compatible formats.	
5.9.6.36 A legend including a clear designation must be issued for all used symbols.	
5.9.6.37 Appropriate block diagrams must be developed in case of complex equipment.	
5.9.6.38 The process flow inside of the equipment must be displayed in a clear and balanced manner e.g. with arrows and text.	
5.9.6.39 The flow directions of the media must be displayed in the drawing.	

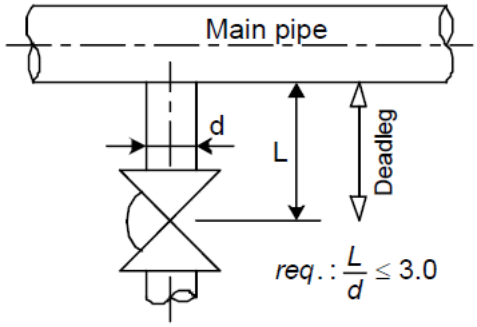
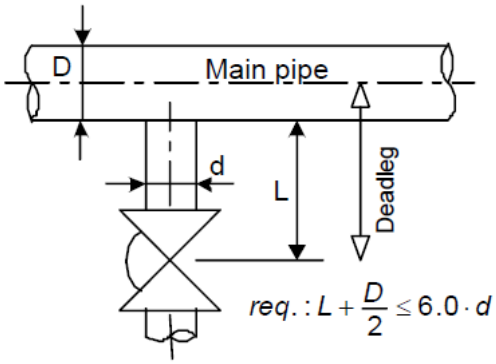
Specifications		Remarks
5.9.6.40	Main dimension and all dimensions of connections to other systems must be indicated.	
5.9.6.41	Equipment with the requirement of drainability must be indicated with slope and direction of slope.	
5.9.6.42	Software ladder logic/ operation and controls flow charts	
5.9.6.43	Biological compatibility certificates of all non metallic parts	
5.9.6.44	The vendor to work out a list showing all documents included in his scope of work and delivery.	
5.9.6.45	All documents require a document control Section listing all versions and indicating executed modifications.	
5.9.6.46	Delivered software must be forwarded on suitable Storage medium in a format suitable for installation. Source codes for Client specific applications must be handed over as electronic files.	
5.9.6.47	If cables have to be pulled by third parties, cable lists with following information are required: unique cable ID-No, cable type, start and endpoint, differentiation between power and control cable, particular requirements.	
5.9.6.48	If the equipment has a control system, all PLC components like I/O-cards and local units like bus nodes, valve terminals or control panel must be listed with information at least about tag name, description, type, vendor's item number and a reference to the appropriate manual with the installation guideline.	
5.9.6.49	Other components next to the PLC like frequency converter, servo controller, electronic cams, transmitter, etc. all single items must be listed with information at least about tag name, description, type, manufacture, and a reference to the appropriate manual books with the installation guideline.	
5.9.6.50	If the equipment contains PCs, the performance data of the PC with processor type/manufacture/tact frequency/hard disk size and RAM must be labeled. Peripheral apparatus like I/O-cards, graphic cards, etc. which do not operate with standard drivers must be indicated and must also be contained information at least about the description, type, manufacture and a reference to the appropriate manual books with the installation guideline.	
5.9.6.51	Supplementing the P&I diagram: A valve position matrix must be developed for complex processes. The conditions of valves and engines must be described in the various process steps.	
5.9.6.52	If the plant is equipped with a PLC, a print of the programming environment must be generated and printed.	
5.9.6.53	Calibration certificate should have validity of at least 12 months from the date of installation	

Specifications	Remarks
5.10 Training Requirement & Support	
5.10.1 A special training for operators, supervisor, and maintenance, electrician staff (min. 5 days each) has to be included in the offer.	
5.10.2 Training must be carried out by qualified personnel. Training documents must be handed over to each participant at the beginning of the training. A training certificate describing the training subjects must be worked out.	
5.10.3 Training documentation to be issued for operator's easy handling and error analysis.	
5.10.4 The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.	
5.10.5 The Vendor shall provide a four (at least 4) hour training course to twelve (12) maintenance people on troubleshooting and repair of the system.	
5.10.6 A concise operating instruction shall be issued containing e. g. pictures for operator's easy understanding of the process.	
5.10.7 Maintenance to be carried out must be clearly and plainly described. Description of the maintenance of all components to be summarized in one document.	
5.10.8 Vendor should specify the in-house strength / capabilities and offer to support for the process validation and optimization of the actual process cycle.	
5.10.9 The Vendor shall provide a twenty-four (24) hour technical support phone number with a maximum of thirty (30) minute response time to calls requesting assistance. Support personnel for this hotline must be knowledgeable and professional.	
5.11 GMP Requirement	
5.11.1 A clear separation between clean and technical area must be realized.	
5.11.2 All utility line shall be properly identified with direction	
5.11.3 All drives, filters, pumps, valves (specially chamber drain) should have easy access	
5.11.4 The sterile filters must be testable for integrity. Vendor should provide the certification with Test procedure for Integrity and no of sterilization cycle in the Certificate.	
5.11.5 For all clean media a sampling valve should be provided at supply and in drain. Sampling valve should be certified 1.5D requirement for Dead leg.	
5.11.6 An appropriate seal must be used for connecting the paneling to the suspended ceiling, clean room walls and floor.	
5.11.7 The front paneling of the system installed in clean room must be gas tight to the technical area of the system	

Specifications	Remarks
5.11.8 The bio-seal provided for aseptic area equipment should be air tight.	
5.11.9 **P&ID Diagram**	
P&I diagrams: are the basis for detailed design, correct functionality, process understanding, maintenance and tracing of the components and instruments in a system. P&I diagrams must therefore be available that have each single component and instrument unambiguously defined by a tag. The plant must be verified to be constructed according to the P&I diagrams and they must subsequently be maintained "as built".	
Components: Every tagged component/instrument on the P&I diagrams must be registered (in databases or lists) with information that supports correct maintenance. Relevant information includes: manufacturer, type, model, dimensions and materials of construction.	
Data sheet, Maintenance instruction: A data sheet and maintenance instructions must be available for each component/instrument type (can be combined in one document).	
Tamper proof Tag numbers: Marking of tags must be executed in a quality that secures durability and resistance to the environment where they are placed (for example temperature, humidity, sunlight).	
Specification:	
• Upon equipment delivery, Vendor shall supply client with a register containing all details of component numbers issued.	
Area of application • Pipes must be laid out according to P&I-diagram. • Where slope on pipes are marked on the P&I diagram, slope must be established with the indicated direction. • Where drainage to drain systems is marked on the P&I diagram, air break must be established. • Placement of components and instruments must be mutually correct according to the P&I diagram. • Components and instruments must be marked with the tag shown on the P&I diagram. • Components and instruments must be drawn on the P&I diagram with the correct symbol. • Components and instruments must be registered on component/instrument lists with correct tag, type and manufacturer.	
Component and instrument databases (or lists) must, for each component / instrument, contain data for • Type • Manufacturer • Model • Dimensions • Materials of construction For each component / instrument type, a datasheet and maintenance instructions must be available.	

Specifications	Remarks
5.11.10 **Sanitary components**	
Sanitory Components: All process equipment (including couplings, fittings and clamps) in contact with non-bacteriostatic media must be of a sanitary type. This facilitates easy and effective cleaning and minimise the risks of microbial growth and other contamination of the product. Whether the equipment can be considered to be sanitary must be assessed based on international, accepted standards for sanitary designs, for example EHEDG Guidelines, 3-A Sanitary Standards or ASME's Bioprocessing Equipment [ASME BPE].	
Specification:	
• All valve and fitting in contact with the media shall be of sanitary type and suitable for aseptic use	
Area of application: The requirements apply to process systems. The requirements are however not relevant to: • Systems with dry gasses. • Self-draining pipe branches in systems with pure steam. a] Tanks, centrifuges, pumps and other process equipment, as well as components and instruments, must be of a sanitary type. b] Couplings, fittings and clamps must be of a sanitary type.	
5.11.11 **Prevention of cross-contamination**	
Cross Contamination: Process systems must be designed so that the risk of cross-contamination is minimised between media that must not get in contact with each other. Prevention against cross-contamination through leaking valves must always be established between CIP systems and other media and always between water systems and other media". Whether the systems must be secured against leaking valves between other media one to another is assessed individually and must be stated in the system's URS or other requirement specifications, and must also be reflected in the design solution.	
Double Block and Bleed: Process systems must be designed so that the risk of cross-contamination is minimised between media that must not get in contact with each other. Prevention against cross-contamination through leaking valves must always be established between CIP systems and other media and always between water systems and other media". Whether the systems must be secured against leaking valves between other media one to another is assessed individually and must be stated in the system's URS or other requirement specifications, and must also be reflected in the design solution.	
Heat exchangers:	

Specifications	Remarks
Heat exchangers must be of the type double-plated heat exchanger or double tube-sheet tubular heat exchanger (Ref section title "sanitary components"), where leaks are detectable on the outside.	
Air break: Drainage towards drains must be secured against reverse suction and contamination with air breaks. Alternatively, a suitable sanitary mechanical device may be used, if the drain connection needs to be closed.	
Area of application: a] The requirements only apply to process systems. Design solutions must be chosen that prevent cross-contamination through leaking valves • Between CIP systems and other media • Between water systems and other media • Between other media one to another if specified in the URS or similar specifications. b] ”Air breaks” towards drain must be visible and at least 25 mm. c] Heat exchangers must be of the type double-plated heat exchanger or double tube-sheet tubular heat exchanger.	
5.11.12 **Deadlegs**	
Deadlegs: The incidence of "deadlegs" in process systems must be minimised to the extent possible to facilitate easy and effective cleaning and minimise the risk of microbial growth and other contamination of the product.	
Design: The design should aim at including as few deadlegs as possible. The deadlegs that cannot be avoided must be designed and constructed to be as small as possible. Deadlegs can result in a "hardest-to-clean area" which must be addressed in the cleaning validation.	
Area of application: The requirement applies to process systems. The requirement is however not relevant to: • Systems with dry gasses. • Dedicated systems with bacteriostatic media. • Self-draining pipe branches in systems with pure steam. a] For deadlegs, one of the acceptance criteria listed below must be fulfilled. As a primary rule, acceptance criterion 1 must be fulfilled. **Acceptance criterion 1** The length (L) of the branch measured from the outer surface of the	

Specifications	Remarks
main pipe must be smaller than or equal to 3.0 x the outer diameter (d) of the branch pipe. I.e.: L/d ≤ 3.0  **Acceptance criterion 2** The length (L) of the branch + the radius of the main pipe (half of the outer diameter, D/2) must be smaller than or equal to 6.0 x the outer diameter (d) of the branch pipe. I.e.: (L+D/2)/d ≤ 6.0  **Acceptance criterion 3** For diaphragm valves ≤ DN 10: The branch (deadleg) must be as small as possible (fulfilment of acceptance criterion 1 or 2 can't be expected).	
5.11.13 **Drain ability:**	
Drain ability: Process systems must be constructed so that they can be drained in connection with cleaning, maintenance and – if relevant – product or media changeover. Pipes must have slope. Components and instruments must be installed so that they are self-draining. For the lowest positioned points in the system ("local minima") a drainage arrangement must be built in, for example drain valve, clamp, pump connection, drain with "air break" or similar.	
Design: Short pipe sections should preferably be designed with a 2% slope and long pipe sections should be designed with a 1% slope. Slopes below 0.5% can only be	

Specifications	Remarks
accepted in exceptional cases.	
Specification:	
• All drains should be at the lowest point of the system for complete drainage.	
• The system shall have sufficient slope to drain out itself completely.	
• All utility pipes specifically pure steam/ water for injection/ condensate should have sufficient slope towards drain for complete emptying of the pipes	
• All drains must be equipped with an air-gap before connected to the drain system on site	
Area of application: The requirements apply to process systems. The requirements are however not relevant to systems with dry gases. Process support systems, utility systems and dedicated process systems with bacteriostatic media must all be drainable to allow easy and safe maintenance, but there is no requirement for a specific slope and the requirements are not subject to formal testing for these systems. **a]** Piping must have at least 0.5 % slope towards drainage points. There must be one or more points through which the piping can be emptied. **b]** The lowest positioned points in the system must all have a drainage possibility. Tanks and other process equipment, as well as instruments and components, must be designed and installed so the system can be drained. This includes that diaphragm valves on horizontal pipe sections must be angled in accordance with the valve manufacturer's instructions (if they cannot otherwise be drained).	
5.11.14 **Decontamination:**	
All surfaces in contact with media must be decontaminated (cleaned) before used in operation. This applies both to systems that are cleaned/CIP'ed as part of normal operations and systems that are not cleaned in operation. Decontamination should remove any contamination generated in connection with fabrication and installation of equipment, etc. The decontamination should not be confused with the cleaning that must be carried out in connection with the daily production. Decontamination does not necessarily ensure that the system is clean enough for production. Inversely, "normal" CIP does not necessarily ensure that the system is decontaminated. The systems must be decontaminated according to a specified procedure before being taken into use. The procedure can for example include successive rinses with NaOH-solutions, citric acid solutions and pure water. CIP procedures with NaOH-solution and HNO_3-solution can often also be used, but is must be assessed case-by-case. The procedure must be preapproved by the Process Owner or his representative. Systems for dry gasses can be decontaminated by blowing with pure process air or pure nitrogen instead of rinsing with liquids.	
Area of application	

Specifications	Remarks
The requirement applies to process systems. For other systems the requirements are intended as guidance and are in such cases not subject to formal tests. a] Systems must be decontaminated before they are taken into use, according to a specified cleaning procedure. The cleaning procedure must be pre-approved by the customer appointed Project Manager and Project QA	
5.11.15 **Pipe marking**	
Piping must be clearly marked indicating what is carried in the pipes and direction of flow. The marking supports correct operation, maintenance, safety and environmental protection. A standard for pipe marking must be prepared covering the system. Typically, an existing standard for the plant/site is used, but a specific standard for the project/system may be agreed.	
Manual operation At certain points in process systems or process support systems wrong pipe marking may cause production errors (for example addition of the wrong media) or cross-contamination in connections with manual operation or other normal, operation-related actions. These critical locations must be specified in the URS (or another requirement or design document). Pipe marking must at these points be verified by qualification (Q). In all other places, pipe marking must be verified by commissioning (C).	
Area of application The requirement applies to all types of systems. a] Pipe installations must be provided with pipe markings according to the standard in effect on the site.	
5.11.16 **Insulation and cladding**	
Insulation and shielding: Insulation of pipes and tanks as well as other cladding and shielding arrangements are often necessary for safety, energy conservation, etc. Insulation and cladding on systems in classified clean rooms must have a sanitary finish.	
Cold/hot pipes Insulation and cladding of cold pipes and tanks in clean rooms must be sufficient to prevent condensation on the outer surface. Systems that are to be sterilised with pure steam must be sufficiently insulated for the required temperature to be achievable. Verification of insulation which is critical in consideration of sterilisation is done during OQ/PQ via identification and check of the coldest points.	
Insulation specifications Insulation/cladding for all systems is selected and dimensioned as part of the detailed design (if a local standard does not exist already) and must be specified in an insulation specification or similar document.	

Specifications	Remarks
Sanitary execution Assessment of what can be viewed as sanitary finish must be based on international, accepted standards for sanitary design, for example EHEDG Guidelines, 3-A Sanitary Standards or ASME's Bioprocessing Equipment [ASME BPE].	
Area of application The requirement applies to all types of systems. However, the requirement for sanitary finish only applies to those parts of the systems that are installed in clean rooms (room classes A, B and C). a] Insulation and cladding of pipe installations and tanks in classified clean rooms must be sanitary with regard to materials and execution/finish. Insulation of piping and tanks must be carried out with the insulation types and dimensions stated in the insulation specification for the system.	
5.12 **Testing requirements**	
5.12.1 FAT	
System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.	
Client must be given thirty (30) working days notice in advance of the testing date. The Vendor must ensure that the equipment to be tested conforms to the design requirements prior to notifying Client.	
FAT shall constitute part of the equipment qualification (Installation and Operational Qualification). They will be conducted at the premises of the Vendor in accordance with written procedures and protocols. The Vendor shall write these procedures and submit them to the client for written approval prior to carrying out the tests.	
The Vendor shall be required to undertake the testing and recording of all data in the test documents, witnessed by the client (and/or their representatives or agents).	
The equipment will be checked for its compliance with the specification. Testing shall include, but not be limited to: ➢ Component check ➢ Documentation check ➢ Visual inspection ➢ Verification of drawings ➢ Dimensional check ➢ Functional checks. **Factory Acceptance Test procedures should include:-** ➢ Accuracy/ performance test shall be done on full integrated line instead of Separate single module.(If applicable) ➢ Description of item and function ➢ Checklist to show equipment properly installed, with services connected,	

Specifications	Remarks
equipment clean etc. ➢ Test equipment used and date of calibration	
In the event of the equipment failing to comply with any of the approved test procedures the Vendor shall, at their own expense, make such alterations and modifications to the equipment as are necessary, following an agreed Change Control Procedure. The test procedure(s) shall then be repeated to verify that the equipment meets the Design and Specification. The costs of any such repeat testing, including all expenses incurred by client Inspection Team, shall be borne by the Vendor.	
Only after satisfactory testing may the equipment be packed and dispatched. The approval of the Factory Acceptance Tests shall not constitute acceptance of the equipment.	
5.12.2 SAT	
The Vendor shall be responsible for checking the equipment installation, performing the start-up, and commissioning the equipment to agreed Site Acceptance Procedures. The Vendor shall write these procedures and submit them to Client for approval prior to carrying out the tests.	
Testing shall include inspection of the installation to check that the equipment has been installed correctly and is the equipment specified. It shall also demonstrate that the equipment will operate as intended throughout all anticipated operating ranges. If applicable the testing will include a repeat of the containment level tests as required during the FAT.	
It will be the Vendor's responsibility to ensure that the equipment conforms to the test procedures, and if a failure occurs, to make such modifications as may be necessary, and to re-test the equipment to prove that the equipment meets the requirements. Any modifications shall be subject to an agreed Change Control Procedure. All expenses of such re-testing shall be borne by the Vendor.	
➢ Site Acceptance Test Procedures should include:- ➢ Description of item and its function ➢ Reference to manuals, guidelines, etc., required to carry out a test ➢ Test equipment used, and date of calibration ➢ Test objectives, methods, and acceptance criteria ➢ Test results ➢ Conclusions, including a clear statement of whether the item has been successfully qualified, or not.	
6.0 Technical Requirement	
6.1 **Basic Technical Requirement**	
6.1.1 The layout must be taken into account when determining the layouts of the units.	

Specifications		Remarks
6.1.2	A proposal of a possible installation layout should be added to the documentation.	
6.1.3	The manufacturer has to give the clear details on the total weight, capacity and dimension of the equipment.	
6.1.4	The heat given off by the unit must be stated (inside the room and through exhaust).	
6.1.5	The construction of the complete system should be described in the documentation in detail.	
6.2	**Level of Automation**	
6.2.1	The equipment should operate with minimum operator involvement. The equipment control panel must be provided with a Human machine interface based on English language with appropriate number of recipe of process parameters.	
6.2.2	The equipment should control automatically all critical parameters and detect failure mode automatically. Critical process parameters and failure modes are listed in the respective URS's.	
6.2.3	Human machine interface must be used to enter the process details, which should appear in the print out. Print out must provide results of all critical process parameters and failure alarms.	
7.0	**Transport, Packaging and storage**	
7.1	Delivery to site in presence of the Vendor's representative. Vendor's representative to ensure proper unloading and safe placement of the equipment with client's consent at site.	
7.2	Packaging and shipping of the equipment must take place only after written approval of the FAT. Release is given after inspection in the factory proving unobjectionable condition of the system.	
7.3	The vendor is responsible for installation. Installation to be coordinated with the client's commissioning supervisor.	
7.4	The freight and placement of equipment at site should be under the vendor's representative supervision. In this aspect, Vendor to depute an engineer who will be at site to oversee the unloading, placement of the equipment in the safe area within the client's place.	
7.5	Making necessary transport and lifting equipment available on site will be in equipment vendor scope.	
7.6	Protection against tilting and sliding must be provided.	
7.7	Transport packaging/identification Identification of transport packaging in clear lettering (indelible and water proof), font height min. 100 mm with following contents:	

Specifications	Remarks
• Manufacturer/vendor of system • Contact person principal • Contact person vendor	
7.8 The installation date agreed in the contract must be strictly followed.	

8.0 Good Engineering Practices Requirements

8.1 Equipment must be fabricated following all Good Engineering Practices. The vendor's Quality System must follow applicable national or international standards, such as ISO 9000. Internal quality procedures shall be available for the User's review.	
8.2 The Vendor shall provide a Quality and Project Plan as part of their proposal.	
8.3 The Vendor shall provide a Project Manager/Responsible person for the project to provide a single communication point with the User.	
8.4 Vendor must generate all applicable documents during all phases of equipment fabrication i.e. design, fabrication, testing and shipment as per applicable standards e.g. GAMP.	
8.5 All sensors, controllers, PLC, transmitters, indicators and any other controller or indicators to read, print or control any of the parameter, will have to be calibrated, traceable to national or international standard. Original calibration certificate along with traceability to be submitted by vendor in their IQ file.	
8.6 All material of construction should have test certificates.	
8.7 Vendor must generate and provide all specifications and test certificates of software used in the equipment control and/or monitoring system.	

9.0 Abbreviation

Terms	Abbrevation
AISI	American Iron and Steel Institute (US standardisation authority)
ASME	American Society of Mechanical Engineers (US standardisation authority)
CFR	Code of Federal Regulation (US)
CIP	Cleaning In Place
CR	Change Request
EDR	Enhanced Design Review
DN	Nominal Diameter
EHEDG	European Hygienic Engineering & Design Group
EN	European Norm

Specifications	Remarks

FDA	Food and Drug Administration (US)
GMP / cGMP	Good Manufacturing Practice / current GMP
HVAC	Heating, Ventilation and Air Conditioning
IRS	Installation Requirement Specification
ISPE	International Society for Pharmaceutical Engineering
P&ID	Piping and Instrumentation Diagram
UNS	Unified Numbering System (metallurgy)
URS	User Requirement Specification
USP	United States Pharmacopoeia
WPS	Welding Procedure Specification

10.0 Definitions

Term	Definition
C-marked requirements	Requirements that by requirement classification are assessed to be verified and documented by “Commissioning”.
Media	Used here as a practical term for all materials/substances that are handled in the systems, i.e. materials / substances having direct or indirect contact with the product. It is typically liquids, but can also be gasses and solid substances.
Process Support Systems	Systems which directly support the process operations. These systems do not have contact with product or media in "process systems", but affect process operations, (such as heating, cooling or vacuum) or they deal with a side effect of the process, such as an air emission or a liquid waste [ISPE BPC].
Tag	A unique, unambiguous number identifying a technical installation location for instruments and equipment/components. The installation location is physically marked with the tag. Note: instruments typically also have an ”ID No”, which is independent of installation location (i.e. Tag ≠ ID No). ID No is used to ensure a traceable calibration.
Technical Discipline Specialist	A person from external company who has the necessary, documented skills, qualifications and/or experience to be able to make sound engineering and scientific assessments within the relevant technical area.
Utility systems	Systems that do not have contact with the product or media in "process systems". They are generally site- or building-wide systems that are not tailored to a specific process. For example plant steam and potable water [ISPE BPC].

11.0 References

Ref.	Title
1.	ASME – Bio-processing Equipment – 2004 (or later version) [ASME BPE]

Specifications		Remarks
2.	AWS D18.2 Guide to Weld Discoloration Levels on the Inside of Austenitic	
3.	Stainless Steel Tube (American Welding Society) [AWS]	
4.	Force Institute, Reference colour charts Report 94.34, chart 1 or 2 level C [Force]	
5.	FDA – Guide to inspection of high purity water systems, July 1993 [FDA Water]	
6.	ISPE Baseline Guide: Vol. 5, Commissioning and Qualification [ISPE C&Q]	
7.	ICH Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients[ICH Q7]	
8.	ISPE Baseline Guide: Vol. 1, Bulk Pharmaceutical Chemicals [ISPE BPC]	
9.	FDA – Code of Federal Regulations, Title 21 [FDA 21 CFR]	
10.	EU Directives 2001/83/EC and 2001/82/EC	

Revision index

Revision	Date	Reason for revision
00	03-02-2014	First draft
01	13-02-2014	Updated as per comments given by HBL on 13-02-2014 by email